UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE FIBROGEN, INC., SECURITIES LITIGATION.

Case No. 21-cv-02623-EMC

ORDER DENYING DEFENDANTS' MOTION TO DISMISS

Docket Nos. 106-107, 109

I. INTRODUCTION

Plaintiffs filed this lawsuit against FibroGen and its current Chief Executive Officer Enrique Conterno, former Interim Chief Executive Officer James Schoeneck, former Chief Medical Officer K. Peony Yu[1], current Chief Medical Officer Mark Eisner, and former Chief Financial Officer Pat Cotroneo[2] (collectively, "Individual Defendants")[3], for violations of Section 10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 promulgated thereunder against the Individual Defendants, for 96 allegedly false and misleading statements between December 20, 2018 and July 15, 2021 (the "Class Period").

Plaintiffs filed this action on behalf of all investors who purchased or otherwise acquired

[1] Dr. Yu was the Chief Medical Officer between April 2016 and December 20, 2020. CAC ¶ 23. She retired as CMO on December 20, 2020 but remained as an Executive Advisor until August 24, 2021. *Id.*

[2] Cotroneo served as the Company's CFO from 2008 to September 6, 2021, but remained as an Executive advisor until March 31, 2022. *Id.* ¶ 28.

[3] Neff was the former CEO of FibroGen during the first nine months of the Class Period. He is not named because he died in August 2019. *Id.* at 3 n. 1.

FibroGen securities during the class period. According to Plaintiffs, Defendants falsely represented the safety and efficacy data of its flagship drug, Roxadustat, and falsely assured investors that the safety data was derived pursuant to FDA-sanctioned analysis. When the deficiencies of the data were revealed, FibroGen's stock price plummeted.

For the reasons set forth below, the Court **DENIES** Defendants' motion to dismiss.

II. FACTUAL & PROCEDURAL BACKGROUND

A. Procedural & Factual Background

This action is a consolidation of a complaint filed by Plaintiff Peifa Xu in this Court and other similar actions brought by purchasers of FibroGen securities elsewhere in this district.[4] *See* Docket No. 75. The amended consolidated class action complaint ("CAC") was filed on April 12, 2021, as alleged below.

1. Defendants' Representations

FibroGen is a biopharmaceutical company whose flagship drug, Roxadustat, is an experimental pill that is designed to treat anemia in patients with chronic kidney disease ("CKD"). Docket No. 97 (CAC) ¶ 4. The current standard of care to treat anemia in CKD patients, Epogen, is only used in severe cases for patients already dependent on dialysis ("DD patients") because it leads to an increased risk of major adverse cardiac events ("MACE"). *Id.* at 3. Accordingly, the key to securing critical FDA approval for Roxadustat was to demonstrate, through Phase 3 clinical trial data, that Roxadustat was at least as effective as Epogen while avoiding the significant safety issues that prevented Epogen from being used to treat incident DD patients and non-dialysis dependent patients ("NDD patients"). *Id.*

Defendants repeatedly asserted that Roxadustat's critical Phase 3 trial results showed that the drug was superior to Epogen and safer than the placebo, which made FDA approval highly compelling. *Id.* ¶ 5. The alleged false and misleading statements generally pertained to (1) Roxadustat's efficacy and safety, (2) whether Roxadustat would receive a "black box" (the FDA's

[4] *Gutman v. FibroGen, Inc.*, No. 3:21-cv-02725-YGR; *Grazioli v. FibroGen*, No. 3:21-cv-03212-CRB; *IBEW Local 353 Pension Plan v. FibroGen, Inc.*, No. 3:21-cv-03396-EJD; *Leonard v. FibroGen, Inc.*, No. 3:21-cv-03370-EMC.

most severe safety warning) label if approved, (3) the non-infringement margin FibroGen used in its safety analysis, and (4) the expressions of optimism about Roxadustat's potential and the likelihood of FDA approval. *Id.*; *see also* Docket No. 91-2.

On the first day of the Class Period, December 20, 2018, FibroGen first released Roxadustat's Phase 3 trial data, and Yu emphasized that its results had "**achieved superiority in efficacy not only against placebo but also over [Epogen].**" CAC ¶ 5. Such statements caused FibroGen's stock price to increase by over 46%, from $41.00 per share at the start of the Class Period to a Class Period high of $59.91 per share on March 1, 2019. *Id.* ¶ 6. On May 9, 2019, FibroGen released MACE safety data, and former CEO Neff highlighted that the results demonstrated a "**statistically significant advantage over [Epogen]**" in the critical incident dialysis group. *Id.* ¶ 5. Conterno also made statements regarding the drug's safety, such as that "**the data [was] extremely clean from my perspective when it comes to cardiovascular safety**" and that "**we showed a 30% reduction in MACE risk**" for incident dialysis patients, which differentiated Roxadustat from its competition. *Id.* He also stated that "**there's no warrant [for a] Black Box**" warning—the "strongest warning the FDA can mandate for prescription drugs"—due to the "compelling" cardiovascular safety data. *Id.* ¶¶ 5, 40. Yu also "set Roxadustat up to be the first anemia drug to avoid a Black Box warning[.]" *Id.* ¶ 5. Defendants reaffirmed these results throughout the end of the Class Period. *Id.*

Furthermore, in a conference call with analysts and investors following a pre-NDA meeting between FDA and FibroGen in July 2019, Neff announced that FibroGen had "**reached an agreement with the [FDA] on the content of the NDA including the cardiovascular safety analysis[.]**" *Id.* ¶ 167. Yu also reaffirmed that "**Phase 3 results confirmed the cardiovascular safety of Roxadustat.**" *Id.*

In November 2019, "FibroGen issued a press release announcing 'Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results'" based on nine studies. *Id.* ¶ 171. The press release specifically stated that Roxadustat "**demonstrate[d] a cardiovascular safety profile comparable with placebo in patients not on dialysis, and comparable or in some cases better than that of**

epoetin alfa[5] in patients on dialysis" by reducing "**risk of MACE by 30% and MACE+ by 34% compared to [Epogen]**" in the crucial incident dialysis population." *Id.*

Leading up to FibroGen's submission of the Roxadustat Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") on December 23, 2019, FibroGen's stock price again surged by over 22%, from $37.01 on November 4, 2019, to $45.30 on December 20, 2019. *Id.* ¶¶ 65–66.

2. Defendants' Gains

AstraZeneca funded the development and eventual FDA approval of Roxadustat. *Id.* ¶ 38. FibroGen's "[p]otential milestone payments" under its agreement with AstraZeneca totaled $1.2 billion—$571 million for "development and regulatory milestones" and $652.5 million for "commercial-based milestones"—and could reach as high as $1.6 billion. *Id.* ¶ 44. FibroGen had stated that its revenue during the Class Period was "generated primarily from our collaboration agreements . . . for the development and commercialization of Roxadustat[.]" *Id.* For example, the submission of the Roxadustat NDA to the FDA on December 23, 2019 triggered a milestone payment from AstraZeneca amounting to $50 million, which comprised approximately 20% of the Company's annual revenues for 2019. *Id.* ¶ 66.

Plaintiffs allege that the Individual Defendants took advantage of FibroGen's inflated stock prices by engaging in insider trading that yielded them proceeds of over $42 million. *Id.* ¶¶ 135–39. Moreover, the Individual Defendants received compensation awards, including bonuses and awards of stock options worth tens of millions of dollars, which were directly tied to FibroGen meeting regulatory and commercial milestones with respect to Roxadustat. *Id.*

3. Disclosures and Consequences

According to Plaintiffs, Defendants' fraud began to unravel when Yu announced his sudden retirement on November 27, 2020. *Id.* ¶ 72. Three weeks later, on December 18, 2020, FibroGen issued a press release that the FDA extended review of the drug by three months. *Id.* ¶ 73. Then on March 1, 2021, FibroGen announced that the FDA would hold an Advisory

[5] Epoetin alfa is a common treatment for anemia in individuals with CKD. *See* Docket No. 29 at 4–6.

Committee ("AdCom") meeting to review Roxadustat's NDA, which was a surprising setback late in the FDA approval timeline. *Id.* at 5. On this news, FibroGen's stock price fell $16.18 per share, or over 32%, to close at $34.35 per share. *Id.* On April 6, 2021, FibroGen provided **"**clarification of certain prior disclosures of U.S. primary cardiovascular safety analyses from the roxadustat Phase 3 program" through a press release. *Id.* ¶ 265. In the press release, FibroGen admitted that its management became aware of "post-hoc changes to the stratification factors[6]" in Roxadustat's Phase 3 trial results—which allegedly amounted to a manipulation of all nine key analyses after the data had been fully unblinded—and that they needed to clarify this with the FDA. *Id.* at 2, 4, 5. Based on the actual "prespecified" FDA analyses, FibroGen could not "conclude that Roxadustat reduced the risk of MACE… or is superior to … [Epogen.]" *Id.* ¶ 8. The press release states in part:

> "As members of senior management were preparing for the upcoming FDA Advisory Committee meeting, **we became aware that** the primary cardiovascular safety analyses **included post-hoc changes to the stratification factors**," said Enrique Conterno, Chief Executive Officer, FibroGen. "**While all of the analyses** set forth below, including the differences in the stratification factors, **were included in the NDA, we promptly decided to clarify this issue with the FDA and communicate with the scientific and investment communities**."
>
> Mr. Conterno continued, "It is important to emphasize that **this does not impact our conclusion** regarding the comparability, with respect to cardiovascular safety, of roxadustat to epoetin-alfa in dialysis-dependent (DD) patients and to placebo in non-dialysis dependent (NDD) patients. We continue to have confidence in roxadustat's benefit risk profile."
>
> . . .
>
> Pooled Cardiovascular Safety Data
>
> As previously disclosed, the Company agreed with the FDA in the pre-NDA meeting that the primary analysis in non-dialysis would be ITT (intention to treat with long-term follow up) and in dialysis would be OT-7 (on-treatment plus 7 days). MACE, a composite endpoint of all-cause mortality, stroke, and myocardial infarction, was the primary safety endpoint agreed on with the FDA. The table below describes the cardiovascular safety results using the post-hoc stratification factors reported at the American Society of

[6] "Stratification factors" refer to grouping clinical trial subjects to ensure balance in treatment arms by factors such as by race, sex, geographic location, and other demographic categories.

> Nephrology conference in November 2019, as well as the analyses with the prespecified stratification factors which have not been previously publicly reported.
>
> . . .
>
> As reflected in the table, the analyses with the pre-specified stratification factors result in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals. For MACE+ in dialysis and for MACE and MACE+ in incident dialysis, the 95% confidence intervals include 1.0. While these hazard ratios remain below 1.0, based on these analyses **we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin-alfa**. These analyses do not change the Company's assessment that roxadustat is comparable to placebo in nondialysis dependent patients and to epoetin-alfa in dialysis dependent patients using MACE to measure cardiovascular safety.

Docket No. 111, Exhibit PP (April 6, 2021 Press Release).

Once Defendants' post-hoc manipulations were corrected, the true data revealed that there were substantial safety concerns—including increased risk of serious afflictions such as thrombosis, seizures, stroke, and even death—that it showed the drug was significantly less effective and less safe than placebo or even Epogen, which already carried the "Black Box" warning. CAC ¶ 7. As a result, Roxadustat's true data failed to support FDA approval in any patient population at all, effectively dooming its FDA approval prospects. *Id.* FibroGen's share price dropped almost in half in two days, from $34.64 per share on April 6, 2021 to $18.81 per share on April 8, 2021. *Id.* ¶ 8.

4. FDA and Market Response

According to Plaintiffs, the FDA had referred to this type of practice as after-the-fact "data-dredging" done in an "attempt to elicit a positive result from a failed study[.]" *Id.* ¶ 79. Since then, numerous market analysts, nephrologists, and news sources condemned FibroGen. *Id.* at ¶¶ 10, 97– 101 ("[t]he re-statement reduced the benefit from [Roxadustat] vs controls in every case [and] erased the appearance of superiority over [Epogen] in incident dialysis patients"; "the fact that [Roxadustat's] Incident Dialysis is no longer 'statistically' superior – is a material change to the profile and [removed] one of the key prior advantages"; "the worst case of data manipulation in years[,]"'; "[t]he fact that all nine analyses across the patient groups looked less favorable for [R]oxadustat after the change raises the suspicion that someone within FibroGen

carefully selected the new criteria to make roxa's profile look better"; "This deeply damages the reputation of FibroGen . . . I feel very misled, and I don't think there is any excuse for this. I don't know how this could happen accidentally."). Even then, Defendants failed to reveal other prespecified FDA analyses—known as "sensitivity" analyses—that revealed that Roxadustat's safety issues were so significant that the drug could not be approved at all. *Id.* ¶ 11.

On July 15, 2021, the FDA's AdCom met to review Roxadustat's NDA and unequivocally concluded that FibroGen's own undisclosed, prespecified sensitivity analyses demonstrated that the drug's efficacy over Epogen was inconclusive at best. *Id.* With regard to safety, the drug caused "greater rates of some important adverse events [] than even [Epogen]," including a higher rate of death and other major side effects. *Id.* Thus, the AdCom voted virtually unanimously against approval for Roxadustat for any patient population, even with a "Black Box" warning. *Id.* The following day, the FibroGen's stock price plummeted over 42%, or $10.49 per share, from $24.84 per share to $14.35 per share on July 16, 2021. In sum, FibroGen's stock price lost 75% of its value in a few short months due to the alleged data manipulation and never recovered. CAC ¶ 13.

III. LEGAL STANDARD

A. Motion to Dismiss

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint that fails to meet this standard may be dismissed pursuant to Rule 12(b)(6). *See* Fed. R. Civ. P. 12(b)(6). To overcome a Fed. R. Civ. P. 12(b)(6) motion to dismiss after the Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544 (2007), a plaintiff's "factual allegations [in the complaint] 'must . . . suggest that the claim has at least a plausible chance of success.'" *Levitt v. Yelp! Inc.*, 765 F.3d 1123, 1135 (9th Cir. 2014). The court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). But "allegations in a complaint . . . may not simply recite the elements of a cause of action [and] must contain sufficient

allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Levitt*, 765 F.3d at 1135 (quoting *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014)). "A claim has facial plausibility when the Plaintiff pleads factual content that allows the court to draw the reasonable inference that the Defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556).

The doctrine of incorporation by reference is distinct from judicial notice. The doctrine "permits a district court to consider documents 'whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the . . . pleadings.'" *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999) (quoting *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir.1994)). The court may incorporate such a document "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003).

B. Securities Fraud Pleading

Rule 10b-5, which implements the anti-fraud provisions of section 10(b) of the Securities Exchange Act, makes it "unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange . . . [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5. To state a claim for securities fraud, a complaint must allege:

> (1) a material misrepresentation or omission by the defendant;
> (2) scienter;
> (3) a connection between the misrepresentation or omission and the purchase or sale of a security;
> (4) reliance upon the misrepresentation or omission;
> (5) economic loss; and
> (6) loss causation.

Halliburton Co. v. Erica P. John Fund, Inc., 134 S.Ct. 2398, 2407 (2014) (citations omitted).

To state a claim for securities fraud, a plaintiff must also satisfy the

> heightened pleading requirements of Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *Police Ret. Sys. v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1057–58 (9th Cir. 2014). "Due in large part to the enactment of the [PSLRA], plaintiffs in private securities fraud class actions face formidable pleading requirements to properly state a claim and avoid dismissal[.]" *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1054–55 (9th Cir. 2008). To satisfy these requirements, a complaint must: (i) "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief ... state with particularity all facts on which that belief is formed," 15 U.S.C. § 78u-4(b)(1)(B); and (ii) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," or scienter, *id.* § 78u-4(b)(2).

Habelt, et al., Plaintiffs, v. iRythm Technologies, Inc., et al., No. 21-CV-00776-EMC, 2022 WL 971580, at *6–7 (N.D. Cal. Mar. 31, 2022). "[F]alsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, and the two requirements may be combined into a unitary inquiry under the PSLRA." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1015 (9th Cir. 2005) (citation and internal quotation marks omitted).

IV. DISCUSSION

A. Judicial Notice and Incorporation by Reference

Defendants seek to introduce various documents related to the alleged statements, and Plaintiffs do not dispute the introduction of these documents. The Court may take judicial notice of Exhibits A–D, F, H, Q, WW, and ZZ-EEE because they are publicly available information, including FibroGen's public filings with the SEC, publicly available documents published by the FDA or submitted to the FDA, available on publicly available websites affiliated with a government agency, or publicly available press releases from FibroGen's partners. *See Lee*, 250 F.3d at 690; *Perkins*, 53 F. Supp. 3d at 1204. Exhibits E, G, I–P, R–VV, and XX–YY may be incorporated by reference. The doctrine of incorporation "permits a district court to consider documents 'whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the . . . pleadings.'" *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999) (quoting *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir.1994)). The court may incorporate such a document "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *United States v. Ritchie*, 342 F.3d 903, 908

(9th Cir. 2003). In this case, Plaintiffs either refer to their contents or quote portions of the documents to support their claims and allegations, thereby forming the basis for Plaintiff's claims. *See Ritchie*, 342 F.3d at 908; *Daniels-Hall v. National Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010) ("Plaintiff directly quoted the material . . . thereby incorporating [the material] into the Complaint.").

B. Securities Fraud

To plausibly allege securities fraud, Plaintiffs must allege with particularity "each statement alleged to have been misleading, the reason or reasons why the statement is misleading," and "facts giving rise to a strong inference that the defendant acted with the required state of mind." *Habelt*, 2022 WL 971580, at *6–7.

1. Safe Harbor and Forward-Looking Statements

The PSLRA's safe harbor provision allows exemptions for certain forward-looking statements. *See* 15 U.S.C. § 78u-5(c). "The PSLRA's safe harbor is designed to protect companies and their officials from suit when optimistic projections of growth in revenues and earnings are not borne out by events." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1142 (9th Cir. 2017). To qualify for protection, the statements must be either: (1) "forward-looking statements that are identified as a forward-looking statement and . . . accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement" or (2) forward-looking statements that were not "made with actual knowledge . . . that the statement was false or misleading." *Id.* §§ 78u-5(c)(1)(A)(i), (c)(1)(B).

> Where a statement is "mixed," *i.e.*, contains both forward-looking and non-forward-looking elements, and where a plaintiff alleges the entire statement is misleading because it omitted material information, the court should determine whether the statement as a whole, not a particular part, is misleading. *See Ivax*, 182 F.3d at 806 ("If the allegation is that the [whole] statement is misleading, then it makes no sense to slice the [statement] into separate sentences.").
>
> The "doctrine reflects nothing more than 'the unremarkable proposition that statements must be analyzed in context.'" *Fecht*, 70 F.3d at 1082 (9th Cir.1995) (internal citations omitted). It "is thus wholly consistent with [the] analysis that whether a statement in a public document is misleading may be determined as a matter of law

> only when reasonable minds could not disagree as to whether the mix of information in the document is misleading." *Id.*

In re Immune Response Sec. Litig., 375 F. Supp. 2d 983, 1033 (S.D. Cal. 2005).

A forward-looking statement is:

> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
>
> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
>
> (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);
>
> (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
>
> (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the [Securities and Exchange] Commission.

15 U.S.C.A. § 78u-5(i)(1).

a. Forward-Looking Statements

Defendants argue that certain statements are forward-looking and therefore not actionable under the PSLRA's safe harbor.[7] *See* Docket No. 107 (Defs. Mot.) at 20. These include statements about (1) the potential approval of the NDA, (2) what label the FDA might require for Roxadustat if approved, and (3) Roxadustat's potential. *Id.* Plaintiffs argue that statements such as Roxadustat "met the safety standards"; "based on what we have seen, we are pretty comfortable with safety"; and "we had all the guidance from the FDA we needed to put together a winning

[7] Dr. Yu also argues that her words in the CAC were selectively presented, taking them out of context to make them sound "misleadingly suggest certainty and guaranteed outcomes rather than her actual forward-looking optimism accompanied by appropriate cautionary remarks." Yu Reply at 11. The Court has reviewed the text of Yu's statements and finds that it is not meaningfully different from Plaintiffs' allegations. In any case, the Court considers any context provided by Yu.

submission"—are misstatements of past or current fact, and thus ineligible for safe harbor protection. Docket No. 114 (Opp'n) at 27.

Further analysis of the listed statements demonstrates that there are elements within them that are not forward-looking. "To the extent that [Defendants] highlights [clinical trial] results that were already available at the time, such statements are not forward-looking and therefore are not eligible for such safe harbor protection." *In re Immune*, 375 F. Supp. 2d at 1034. Here, the alleged statements are based on existing and allegedly manipulated data. Statement #1 is such an example:

> We are excited to have achieved superiority in efficacy not only against placebo but also over epoetin alfa in our studies… [t]hese results support [R]oxadustat's potential to bring clinical benefit over current standard of care, such as reducing blood transfusion risk in patients on dialysis and those not on dialysis, and to improve patient access to anemia therapy with a new convenient oral therapeutic.

See Docket No. 107-1 (Statement Chart), Statement #1; *see also* Statement # 63 ("[Regarding the NDD analyses] Roxadustat 'has the right efficacy safety profile to be able to have a really good uptake in the NDD setting and be able to be a catalyst for the overall expansion of that market'"). The "potential" of Roxadustat is based on the assertions that *existing* clinical studies achieved superiority in efficacy against both placebo and epoetin, which are not forward-looking.

Statements about the potential approval of the NDA are similarly based on existing data. For example, Defendants characterize Statement #5, which emphasizes "positive . . . results" that "support [FibroGen's] NDA[,]" as forward-looking. Defs. Mot. at 20; Statement Chart, Statement #5. However, the full text makes clear that the statement was based on the clinical data:

> "In these 5 U.S. ROW studies, we enrolled a total of 7,721 patients composed of 3,917 in dialysis and 3,804 in non-dialysis. **All of these studies *have positive top line results***. We and our partners believe the results from these trials to ***support our NDA [to the FDA]*** as well as our marketing authorization application, or MAA, to the European Medicines Authority, or EMA. The fully adjudicated MACE results, including completing adjudication procedures to enable consistent safety assessment without bias, are to be included in our planned NDA to the FDA. **Completion of the full adjudication procedures is on track for the second quarter of 2019**.
> …
> At this point, based on our review of the data to date and our

> discussions with counterpart teams at AZ and Astellas and discussions with our partners' leadership ***there is a strong conviction to move ahead to file the NDA*** and MAA this year."

Statement Chart, Statement #5 (emphasis added); *see also* Statement #11 ("[T]hese positive safety data give us confidence as we progress in preparation for the U.S. NDA.").

Furthermore, statements are not forward-looking if they "refer to *past* interactions with the [FDA], and do not merely express optimism or confidence about FDA approval." *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 816–17 (C.D. Cal. 2011) (finding that the statement "meeting [with the FDA] . . . seemed to be very supportive" was not forward-looking"). Statements that FibroGen had a "very good pre-NDA meeting with the FDA on [R]oxadustat[,]" that the FDA reached an agreement "on our proposed pooled MACE analysis[,]" and that FibroGen was "very pleased with the agreement [with the FDA] on the primary safety analysis of our primary cardiovascular safety endpoint in NDD" are not mere expressions of optimism that would qualify for safe harbor protection. Statement #25–27. They are based on past interactions with the FDA.

Statements about favorable labeling similarly highlight the *existing* clinical trial analyses. *See, e.g.*, Statement #51 ("I feel it basically shows that the product is safe because of the safety profile when it comes to CV comparable to placebo . . . [I]n [DD], when it comes to incident dialysis, we do show an actual significant benefit, well, with a 30% reduction in MACE . . . When I put those two reasons together, look at the compelling nature of our data, and I feel that . . . there's no warrant [for a] Black Box . . ."; Statement #42 ("we have the optionality of an upside of not being able to get [a black box], given the data that we have"). These statements about Roxadustat's potential, approval, and labeling cannot be meaningfully separated from the allegedly manipulated clinical analyses and past interactions with the FDA. Statements that mix past or current facts with forward-looking optimistic statements do not qualify for safe harbor protection. ("[A] defendant may not transform non-forward-looking statements into forward-looking statements that are protected by the safe harbor provisions of the PSLRA by combining non-forward-looking statements about past or current facts with forward-looking statements about projected revenues and earnings."). *In re Quality Sys*, 865 F.3d at 1141. The statements at issue here are ineligible for safe harbor protection. *In re Immune*, 375 F. Supp. 2d at 1034. Because the

alleged statements are not forward-looking and does not qualify for safe harbor protection, the Court need not discuss whether the statements were accompanied by meaningful cautionary language.

b. Actual Knowledge

Defendants also argue that the alleged statements are also protected under the second prong of the safe harbor, as Plaintiffs fail to allege that Defendants had "actual knowledge" that any statement was false or misleading when made. Docket No. 115 (Defs. Reply) at 20 (citing *Intuitive Surgical*, 759 F.3d at 1058; 15 U.S.C. § 78u-5(c)(1)(B); *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1070 n.5 (N.D. Cal. 2001)). However, this argument is unconvincing because the allegation that the Defendants manipulated the clinical data to obtain more favorable analyses implies knowledge. *See* Opp'n at 28.

2. Opinions and Puffery

Under securities law, "[s]tatements of mere corporate puffery, vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers, are not actionable because professional investors, and most amateur investors as well, know how to devalue the optimism of corporate executives." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014) (internal quotation marks and citation omitted). "A statement is considered puffery if the claim is extremely unlikely to induce . . . reliance. Ultimately, the difference between a statement of fact and mere puffery rests in the specificity or generality of the claim." *Newcal Indus., Inc. v. Ikon Off. Sol.*, 513 F.3d 1038, 1053 (9th Cir. 2008).

As for opinions, there are "three different standards for pleading falsity of opinion statements" in the Ninth Circuit. *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615 (9th Cir. 2017).

> First, when a plaintiff argues there are material misrepresentations, she must "allege both that the speaker did not hold the belief she professed and that the belief is objectively untrue." Second, when a plaintiff "relies on a theory that a statement of fact contained within an opinion statement is materially misleading, the plaintiff must allege that the supporting fact the speaker supplied is untrue." The third theory relates to omissions, which are not relevant to this analysis.

In re QuantumScape Sec. Class Action Litig., No. 3:21-CV-00058-WHO, 2022 WL 137729, at *15 (N.D. Cal. Jan. 14, 2022) (citations omitted) (quoting *Align Tech.*, 856 F.3d at 615).

Defendants argue that the alleged statements constitute corporate optimism, on which "investors do not rely." Defs. Mot. at 19 (citing *Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *11 (N.D. Cal. Sept. 27, 2012)); *see generally* Docket No. 109 (Yu Mot.). This includes statements that: the data and interaction with the FDA were "positive," "good," "favorable," "right," "encouraging," "extremely clean," "excellent," "robust," "reassuring," or "strong," the NDA submission was "complete," the Company found the safety data "compelling," and felt "comfortable," "confident," "excited," "pleased," or "good" about it. *Id.* at 19–20 (citing *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 869 (N.D. Cal. 2004) (statements that results were "very positive" or the company had a "strong" product "constitute run-of-the-mill corporate optimism on which no reasonable investor would rely"); *Jasin v. VIVUS, Inc.*, 721 F. App'x 665, 667–68 (9th Cir. 2018) (approval "looking good" was a "mildly optimistic, subjective assessment" insufficient to plead fraud).

Furthermore, Defendants contend that statements that a product had an "excellent" or "compelling" risk/benefit profile are opinions that "inherently reflect the speaker's assessment of and judgment about the underlying circumstances." *Id.* (citing *Markette v. XOMA Corp.*, 2017 WL 4310759, at *4 (N.D. Cal. 2017); *In re LifeLock, Inc. Sec. Litig.*, 690 F. App'x 947, 951 (9th Cir. 2017) (what defendants "believe[d]" or "fe[lt]" are opinions). Defendants argue that all statements interpreting the safety data were opinions and were framed as beliefs rather than objective conclusions and that any interpretations of data are essentially opinions. *Id.* at 14 (quoting Statement Chart, Statement #23 ("we *believe* our MACE results in dialysis and in non-dialysis also support the conclusion of no increased cardiovascular safety risk") (emphasis in original)). Therefore, Defendants point out that Plaintiffs fail to allege the opinions were not genuine. According to Defendants, "[FibroGen's] disclosures about the pooled safety analyses cannot form the basis of a fraud claim unless the CAC pleads with particularity that the statements were not 'sincerely held.'" Defs. Reply at 17 (quoting *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011)).

It is true that "[w]hen valuing corporations, ... investors do not rely on vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010). However, this Court has previously explained:

> "When determining whether statements amounted only to puffery, the court must analyze the context in which the statements were made." Even a statement of opinion or an expression of corporate optimism may be deemed actionable in certain circumstances because "there is a difference between enthusiastic statements amounting to general puffery and opinion-based statements that are anchored in 'misrepresentations of existing facts.'" As the Ninth Circuit stated in *Casella v. Webb*, 883 F.2d 805, 808 (9th Cir.1989), "What might be innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation." Accordingly, the Court may not assess the statements listed in the FAC in a vacuum, "plucking the statements out of their context to determine whether the words, taken per se, are sufficiently 'vague' so as to constitute puffery," but rather will examine the entire statement and its circumstances to determine if it is actionable.

Mulligan v. Impax Lab'ys, Inc., 36 F. Supp. 3d 942, 966 (N.D. Cal. 2014) (citations omitted). This Court then further explained:

> To be sure, the statements include superlatives which are indicative of the speaker's opinion and are often seen in "puffing" statements—for example, references to "significant" manufacturing and quality control improvements. **However, as the Court found above in its discussion over whether these statements are "forward-looking," the vast majority of the statements identified in the FAC contain factual representations at their core—**that Defendants had responded to the FDA Warning Letter by instituting various changes to the manufacturing and/or quality control procedures or processes. Similarly, **that certain statements are predicated with indications that the speaker "thought" or "believed" a given statement does not change this result**.

Id. at 967 (citations omitted).

Likewise, in this case, Defendants' expressions of confidence are in the context of discussing the safety analyses of the existing data. For example, after describing the efficiency and safety as "robust," Yu described that Roxadustat-treated patients had lower transfusion risk than epoetin and lowered MACE+ risk in the dialysis patient pool. *See* Statement #44. Similarly, the descriptions "positive," "good," "favorable," and "right" for the safety profiles were later followed with "comparable to placebo," "we showed non-inferiority" and that the drug "basically

reduced cardiovascular outcomes in [the incident dialysis] population." Statements #63, 65. The CAC is replete with such objective statements, "such as claims that Roxadustat 'reduced risk of MACE by 30%' in the crucial incident dialysis population; and that the analyses were 'agreed [upon] with the FDA.'" CAC ¶¶ 158, 167, 171.

Yu's statements are similarly premised on facts such as "Roxadustat was at least non-inferior to epoetin alfa even in the conversion stable dialysis patients" and "we had already talked with the FDA about [the] analytical plan, and we had made the agreement on the analysis plan . . . and the numbers I had just presented, were based on the agreed upon analysis plan that we have made with the FDA."[8] Statements #18, 35. Yu argues that it is a stretch to assume in hindsight that her statements referenced the allegedly manipulated stratification factors and not the specific analytical methods actually discussed at the pre-NDA meeting in July 2019. *See* Docket No. 116 (Yu Reply) at 14. However, "the numbers [that Yu] had just presented[,]" seem to have pertained to the analyses containing the post-hoc changes. *See* CAC ¶ 27. As such, investors may have reasonably equated the "analytical plan" with analyses containing the alleged post-hoc changes.

Like statements about safety, Plaintiffs argue that Defendants overstated Roxadustat's efficacy by claiming that Roxadustat had "achieved superiority in efficacy not only against placebo but also over [Epogen]," and had "efficacy benefits" including "patients had a 33% reduction in the risk of blood transfusion compared to epoetin [alfa]" and "improvement in quality of life." Opp'n at 23 (citing CAC ¶¶ 148, 163, 187, 189, 190). Plaintiffs argue that Defendants were not permitted under the federal securities laws to make glowing statements about Roxadustat's superior efficacy while concealing numerous significant safety issues that wholly eclipsed any such claims. *Id.* (citing *Oklahoma Police Pension & Ret. Sys. v. LifeLock, Inc.*, 780 F. App'x 480, 483 (9th Cir. 2019) ("companies mislead investors when they tout their products' capabilities but fail to disclose significant flaws that undercut those capabilities"); *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1010 (9th Cir. 2018) ("once [the Company] chose to tout the apparently positive [] results, [the Company] had the obligation also to disclose that they

[8] Again, Yu argues that Plaintiff put her statement out of context to suggest certainty and guaranteed outcome, but the full text as presented here does not seem out of context.

were likely unreliable")). Defendants, while allegedly concealing the fact that Roxadustat was significantly less safe than placebo and even Epogen, touted Roxadustat's efficacy. Opp'n at 23. Plaintiffs allege that in reality, the FDA determined that the claimed reduction in blood transfusions versus Epogen was "unclear" and likely nonexistent at the untested lower doses—and the AdCom found there was "a surprising lack of improvement in quality of life" in patients taking Roxadustat. *Id.* (citing CAC ¶¶ 104, 112, 146, 191, 194).

Defendants argue that Plaintiffs conflate efficacy with the FDA's risk-benefit analysis, which assesses whether the benefits (efficacy) of a product warrant its risk (safety). Defs. Mot. at 14. According to Defendants, it is not wrong that a drug is effective and also has side effects. Defs. Reply at 15. Therefore, issues with safety do not render statements about efficacy false.[9] *Id.* According to Defendants, the FDA had confirmed the contrary–that "[R]oxadustat's efficacy is not in question" as "[a]ll studies . . . demonstrated efficacy." Defs. Mot. at 14 (citing Ex. VV (FDA Brief to AdCom) at 7); Yu Mot. at 4 (citing same).

At the hearing, parties clarified that efficacy and safety are inevitably intertwined because the key to efficacy is safe dosing levels. While Defendants contend that Roxadustat's efficacy was demonstrated, Plaintiffs have alleged that the claimed reduction in blood transfusions was unlikely at lower doses. CAC ¶¶ 104, 112, 146, 191, 194. As such, statements of efficacy may nevertheless have been false and misleading if they were based on unreasonably high dosing levels. In short, Plaintiffs have alleged a plausible claim of falsity that are not mere opinions and puffery.

Finally, Defendants point out that mere disagreements with the type of analysis used and the interpretation of a clinical trial result cannot be false and misleading. *See* Defs. Mot. at 18 (citing *In re MELA Scis., Inc. Sec. Litig.*, No. 10 CV 8774 VB, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal.

[9] Defendants also cite *Kovtun*, 2012 WL 4477647, *9 to argue that issues with safety do not render statements about the separate concept of efficacy false. Defs. Reply at 15. Defendants incorrectly attempt to argue that this Court previously rejected a plaintiff's attempt to challenge statements regarding efficacy by identifying safety risks. However, this Court simply found that there was no falsity in both the efficacy and safety statements and did not discuss the relationship between efficacy and safety. *See Kovtun*, 2012 WL 4477647, *22.

2001)). However, what Plaintiffs allege goes beyond merely using different statistical analyses and differences in interpreting the results of the clinical trial; the crux of the complaint is that Defendants actively *manipulated* the data post-hoc. *See* CAC ¶ 247 (Defendants "submitted the true prespecified analyses to the FDA in the Roxadustat NDA, but never publicly disclosed them, and instead attempted to pass off their 'post-hoc' manipulated data to investors as the real data for over two years").

However, general statements not premised on factual misrepresentations, such as: "there is a strong conviction to move ahead to file the NDA and MAA this year," "we have a high level of conviction on the overall submission, the strength of our data," "walking out of [a meeting with the FDA after the NDA submission], we felt that we had all the guidance from the FDA we needed," that "interaction with the FDA was positive" are not based on facts but on Defendants' personal impressions. Statement Chart, Statement # 34, 57; Defs. Yu Reply at 13. Therefore, Statements #5, 34, 57, 60, 67, and 73 are opinions that cannot be objectively untrue.

In sum, with the exception of some general statements about how the NDA meeting felt to FibroGen and Defendants' confidence in the NDA submission, other statements about the safety and efficacy of Roxadustat and the potential for NDA approval are not mere puffery or opinions and, therefore, actionable.

3. Pleading Falsity with Particularity

"Falsity is alleged when a plaintiff points to defendant's statements that directly contradict what the defendant knew at that time." *Khoja*, 899 F.3d at 1008. *See In re Twitter, Inc. Sec. Litig.*, No. 19-CV-07149-YGR, 2020 WL 7260479 (N.D. Cal. Dec. 10, 2020), *aff'd sub nom. Weston Fam. P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611 (9th Cir. 2022) ("[P]laintiffs . . . fail to suggest that defendants' statements directly contradicted what they plausibly knew at the time and were therefore false."). The quote from *Khoja* has not been explained by the Ninth Circuit. *See Weston Fam. P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 619 (9th Cir. 2022). But courts in this district have elaborate on this language when discussing falsity:

> The cases plaintiffs cite in support of its omission theory are illustrative and bolster the argument for dismissal. In each of these cases, the plaintiffs were found to have pleaded falsity with

> particularity under an omissions theory precisely because defendants in those cases were already in possession of information that directly contradicted their public statements when made. *See Khoja*, 899 F.3d at 1008 ("Falsity is alleged when a plaintiff points to defendant's statements that directly contradict what the defendant knew at that time.").
>
> In *Khoja*, for example, defendants were touting positive interim results of a study without also disclosing that the FDA had already explicitly warned defendants that these same results had "a high degree of uncertainty" and were therefore unreliable. . . . Contrast this with the alleged omissions here, where plaintiffs have brought forth no facts to show defendants knew the NDA was destined for rejection in light of their alleged failure to reference 6-and 9-month toxicology studies.

Immanuel Lake v. Zogenix, Inc., No. 19-CV-01975-RS, 2020 WL 3820424, at *9 (N.D. Cal. Jan. 27, 2020). "Even if a statement is not false, it may be misleading if it omits material information." *Id.* at 1008–09.

For affirmative representations, "to properly allege falsity, a securities fraud complaint must now specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, state with particularity all facts on which that belief is formed." *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 877 (9th Cir. 2012) (internal quotation marks, citation, and alteration omitted). For omissions, "it must affirmatively create an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). The securities laws "do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44, 131 S.Ct. 1309, 179 L.Ed.2d 398 (2011) (internal quotation marks, citation, and alteration omitted).

First, Defendants argue that the CAC fails to plead falsity because it simply does not allege that any data was falsified or that any individual defendant did not sincerely believe that they were reasonable interpretations of the data. Defs. Reply at 19; Defs. Mot. at 15. However, the CAC alleges that Defendants had "manipulated" Roxadustat's clinical trial data, and such post-hoc analyses were "improper" and considered little more than "after-the-fact 'data-dredging'" (misuse

of data analysis). CAC ¶ 79, n.3; Opp'n at 15. The allegations of manipulation imply that the data was falsified and that Defendants knew so.

Defendants next argue that it was not misleading for FibroGen to share its interpretation of the data based on only certain analyses submitted in the NDA because there is no "affirmative duty to disclose any and all material information." Defs. Mot. at 17, n.15 (quoting *In re Rigel*, 697 F.3d at 880 n.8 ("[A] company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant."). This argument also fails because Plaintiffs' allegation is not that Defendants simply omitted some information but that analyses were manipulated to show a reduction in MACE risk when there was no evidence of it.

Defendants also argue that allegations must specifically challenge either the accuracy of the numbers contained in the analyses or the conclusions drawn from them. Defs. Mot. at 17 (quoting *In re Regulus Therapeutics Inc. Sec. Litig.*, 406 F. Supp. 3d 845, 857 (S.D. Cal. 2019) (dismissing claims where the plaintiff offered only "vague and impressionistic . . . allegations regarding the contradictory . . . results purportedly held by Defendants")). According to Defendants, the CAC pleads no facts that demonstrate that the underlying clinical data did not support the results that FibroGen disclosed. *Id.* at 17–18. However, Plaintiffs sufficiently challenge with specificity the facts and conclusions drawn from the clinical trial data by Defendants. For example, they allege that "contrary to Defendants' statements above highlighting the purported statistically significant 30% and 34% reduction in MACE and MACE+ risk in the crucial incident dialysis population—under Roxadustat's true, undisclosed prespecified analyses, there was no evidence of any purported reduction of MACE risk in this population at all." CAC ¶ 191.

As such, Defendants' general arguments fail. Arguments regarding specific allegations are discussed below.

a. The Pre-NDA Meeting

Regarding any alleged statements falsely representing an agreement with the FDA, Defendants point out that FibroGen was transparent in stating that there was no such agreement

about the analytical framework for the pooled safety analyses until the pre-NDA meeting in July 2019. Defs. Mot. at 15–16 (citing Ex. J at 6 ("[W]e have not yet spoken with the FDA. . . . [T]here is a discussion planned with the FDA about these various analyses.")). Therefore, any such statements could not have been false. FibroGen did not purportedly follow the "analyses required by the FDA" as no such analyses existed until after the statements were made. *Id.* In fact, the analytical framework was developed with the FDA post-hoc. *Id.* at 18.

However, this fact does not create a meaningful difference. Plaintiffs do not allege that Defendants claimed that the framework for their analyses was approved by the FDA prior to July 2019. Rather, Plaintiffs assert that the alleged manipulations themselves were misleading. As such, Defendant's argument is a moot point. Opp'n at 17–18 (arguing that the data they showed in May 2019, prior to the pre-NDA meeting, was manipulated data because they used the post-hoc stratification factors rather than the "prespecified" factors). Any discussion of the "agreement" with the FDA postdates July 2019.

b. The April 6, 2021 Press Release

The April 6 press release states in part:

> "As members of senior management were preparing for the upcoming FDA Advisory Committee meeting, **we became aware that the primary cardiovascular safety analyses included post-hoc changes to the stratification factors**," said Enrique Conterno, Chief Executive Officer, FibroGen. "**While all of the analyses** set forth below, including the differences in the stratification factors, **were included in the NDA, we promptly decided to clarify this issue with the FDA** and communicate with the scientific and investment communities."
> Mr. Conterno continued, "It is important to emphasize that **this does not impact our conclusion regarding the comparability, with respect to cardiovascular safety, of roxadustat to epoetin-alfa in dialysis-dependent (DD) patients and to placebo in non-dialysis dependent (NDD) patients**. We continue to have confidence in roxadustat's benefit risk profile."
>
> FibroGen continues to prepare for the FDA Advisory Committee meeting and will work closely with the FDA to bring this important new treatment to patients living with anemia of CKD.
>
> **There is no change in the underlying roxadustat data, or to the efficacy analyses from the Phase 3 program.** The Company has begun a comprehensive internal review to ensure such issues do not occur in the future.

April 6, 2021 Press Release.

The press release also included the following chart comparing the figures for the post-hoc stratification factors with the unreported pre-specified stratification factors:

	Analyses with post-hoc stratification factors	Analyses with pre-specified stratification factors
	HR (95% Confidence Interval)	HR (95% Confidence Interval)
Non Dialysis (OLYMPUS, ANDES, ALPS N=4,270); ITT		
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)
MACE+	1.04 (0.91, 1.18)	1.07 (0.94, 1.21)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)
Dialysis Dependent (HIMALAYAS, SIERRAS, ROCKIES N=3,880); OT-7		
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)
MACE+	0.86 (0.74, 0.98)	0.91 (0.80, 1.05)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)
Incident Dialysis (N=1,526); OT-7		
MACE	0.70 (0.51, 0.96)	0.82 (0.60, 1.11)
MACE+	0.66 (0.50, 0.89)	0.78 (0.59, 1.02)
ACM	0.76 (0.52, 1.11)	0.82 (0.57, 1.18)

Id.

According to Plaintiffs, Defendants' April 6 press release was an admission that they manipulated the clinical trial results by making "post-hoc changes to the stratification factors." Opp'n at 15–16. Defendants dispute Plaintiffs' characterization that the April 6 press release constitutes an admission because (1) there was "no change in the underlying Roxadustat data, or to the efficacy analyses from the Phase 3 program" and (2) the submission to the FDA expressly contemplated that the data would be analyzed using both study-specific (i.e., "pre-specified") and "other common" stratification factors. Defs. Reply at 16; Yu Reply at 3. Furthermore, FibroGen told investors throughout the Class Period that it would be analyzing the data in many ways. *Id.* As such, Investors could not have been misled into thinking that there was only one way to analyze the data or that FibroGen had not conducted any other analyses. *Id.* Defendants argue that the fact that new management decided on a different set of analyses does not make the previously shared information false. Defs. Reply at 17. Yu also points out that in May 2019, when the data was unblinded, FibroGen had told the public that there were some issues in the NDD studies that would be discussed with the FDA at the pre-NDA meeting and that after the pre-

DNA meeting, FibroGen had come to an agreement with the FDA about this issue.[10] Yu Reply at 4.

However, although the press release does not seem to be an explicit admission that Defendants manipulated the data, it constitutes an admission at least to the extent that they made "post-hoc changes to the stratification factors." April 6, 2021 Press Release. According to Plaintiffs, these changes were so significant that FibroGen needed to promptly "clarify this issue with the FDA" to "make sure that it was clear which analyses used which factors, prespecified and post-hoc" in 2021. Opp'n at 15–16 (quoting CAC ¶ 8). The press release admitted that "based on these [unmanipulated FDA prespecified] analyses we cannot conclude that Roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to [epoetin-alfa]." April 6, 2021 Press Release. According to Plaintiffs, "investors had been completely unaware of this material information, as Roxadustat's true FDA-prespecified data '[had] not been previously publicly reported.'" Opp'n at 15–16. These alleged facts suggest that the post-hoc changes (eventually admitted to on April 6) were material, undisclosed facts to both the FDA and investors prior thereto and support an inference of falsity.

c. Impact of the Post-Hoc Changes

Defendants argue that the alleged statements were not false because FibroGen reiterated in the April 2021 release the same conclusions regarding comparative MACE risk in the NDD and DD trials. Defs. Mot. at 17. Although the MACE risk disclosed on April 6 differed slightly from those disclosed before, the additional analyses did not change the conclusion that there was no clinically meaningful difference in risk of MACE between Roxadustat, Epogen, and placebo. *Id.* Defendants further point out that the FDA also concluded that there was "no significant difference in the risk of MACE" between the drug and its comparators and that "[t]he findings were qualitatively similar, regardless of the stratification factors."[11] *Id.* (citing Docket No. 111, Ex. XX

[10] Yu also points out that she stepped down as FibroGen's CMO in December 2020, prior to this April 6, 2021 press release. Yu Reply at 3. However, considering that the press release constitutes an admission by FibroGen that post-hoc changes were made while Yu was still at FibroGen, Yu's involvement in the manipulation of the analyses is still plausibly alleged.

[11] Defendants also point out that there was never any agreement with the FDA that FibroGen

at 169–71; FDA Brief to AdCom at 47); Yu Reply (citing same). Plaintiffs respond that FDA never agreed that there was no significant difference in the risk of MACE between the drug and its comparators in NDD and DD patients. Opp'n at 18.

Although statements that Defendants cite indicate that the post-hoc changes may not have made a large difference, they do not show that the FDA concluded that there was no difference in MACE risk. Defendants cite an FDA Briefing Document prepared on July 14, 2021 for the advisory meeting held on July 15, 2021. *See* FDA Brief to AdCom at 1 ("The MACE meta-analysis included pre-specified, trial-specific stratification factors. The applicant also provided results using common stratification factors defined post[-]hoc. The findings were qualitatively similar, regardless of the stratification factors."). However, a Briefing Document is not a conclusive result, especially when the AdCom allegedly "overwhelmingly" voted against the drug. *See* Opp'n at 19. Plaintiffs assert a plausible claim of falsity.

Defendants also refer to a record of the actual FDA advisory committee meeting. *See* Defs. Mot. at 17. Although Defendants selectively quote the portion that there was "no significant difference in the risk of MACE" for the NDD population, Dr. Unger subsequently stated that there was an increased risk of MACE in other studies. *See id.* Dr. Ellis Unger's remarks state in part:

> In summary, there was considerable difference between the estimated hazard ratios for the primary on-study analysis and the OT-plus-7 sensitivity analysis. **In the NDD population, the treatment policy analysis results suggest no significant difference in the risk of MACE relative to placebo**. **On the other hand, the results from the on-treatment or the OT-plus-7 analysis suggest an increased risk of MACE for the roxadustat arm compared to placebo**. In summary, in the DD population, results suggested no significant difference in the risk of MACE while subjects were receiving the assigned treatment. **However, the on-study analysis suggests an increased risk of MACE relative to ESA**, and the direction of such risk was also consistent in a trial that was not considered for meta-analysis.

Docket No. 111, Ex. XX at 169–71. Furthermore, Plaintiffs allege that this manipulation was so material that Defendants had to retract their submission to a medical journal. Opp'n at 15–16 (citing CAC ¶¶ 84–85). Accordingly, Plaintiffs have plausibly alleged that the post-hoc

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would submit data regarding the incident dialysis subgroup as part of the NDA nor how the data would be analyzed. Defs. Mot. at 17–18.

manipulations were material.

d. Significance of Post-hoc

Parties also dispute the significance of "post-hoc changes to the stratification factors" admitted in the April 6, 2021 press release. Defendants argue that a focus on "post-hoc" is a red herring because the entire analytical framework was "post-hoc," based upon agreement with the FDA at the July 9, 2019 pre-NDA meeting. Defs. Mot. at 7. FibroGen also never commented on the stratification factors to be used in the analyses. Defs. Reply at 13.

Plaintiffs have sufficiently alleged that the deviations from the prespecified stratification factors were improper post-hoc changes. According to Plaintiffs, the statistical plans for the trials were submitted to the FDA in August and September 2018, before the Phase 3 data were unblinded and well before the July 2019 pre-NDA meeting. Opp'n at 18. The purpose of the pre-NDA meeting was not to decide on a brand-new statistical analysis of the data and change the fully unblinded results of the prespecified analyses post-hoc, but to determine which of these prespecified plans (the "ITT" or "OT+7" analyses) would be used as the primary analyses for the NDA. *Id.* at 18, n.9. Both analyses were to be conducted pursuant to prespecified stratification factors without manipulations. *Id.* These facts are sufficient to plausibly allege that the post-hoc changes were improper.

e. The Non-Inferiority Margin

Plaintiffs allege that Yu and Conterno (and non-defendant Neff) falsely implied to investors that the FDA had agreed to a non-inferiority margin of 1.3 for the pooled safety analyses because they referred to it as a "standard," "reference," or "commonly applied" margin[12]. Opp'n at 19–20. Based on this margin, Defendants "falsely stated that Roxadustat had achieved noninferiority because its hazard ratio was below this 1.3 threshold which the FDA would supposedly be looking for in reviewing Roxadustat's MACE results." *Id.* This was allegedly

[12] The goal of the safety trials was to show that Roxadustat was "non-inferior" relative to Epogen or placebo, meaning that Roxadustat did not cause more adverse safety events compared to them. CAC ¶ 47. This was measured by hazard ratios—the smaller the hazard ratio, the safer the drug. *Id.* ¶ 48. The non-inferiority margin is the threshold below which it can be established that the new drug is not unsafe. *See id.* A hazard ratio greater than the threshold would mean that the drug is unsafe for approval. *See id.*

misleading because the FDA had already expressly rejected 1.3 non-inferiority margin for the reason that "it was defined [by FibroGen] after the results of the study were known" – *i.e.*, post-hoc. Opp'n at 20; CAC ¶¶ 55, 110, 152. Instead, the FDA had told FibroGen that it "had a goal of 1.25" during the pre-NDA meetings, as confirmed by Dr. Farrell, who was personally involved in the negotiations. Opp'n at 20–21 (quoting *In re MannKind*, 835 F. Supp. 2d at 809–10 (statements "that the FDA had accepted, or blessed, or agreed to the Defendants' [] methodology— which are shown to be false by a later revelation demonstrating that the FDA had not, in fact, done any such thing—do not constitute 'fraud-by-hindsight'")).

Plaintiffs' allegations are plausible only to the extent that the CAC alleges that data was manipulated to show a lower margin, but not to the extent that Defendants falsely implied to investors that the FDA had agreed to a non-inferiority margin of 1.3. This is because none of the relevant alleged statements imply an agreement with the FDA regarding the non-inferiority margin:

- FibroGen stated that the "ITT [intention-to treat]" method was "among the several statistical methods that we will discuss with the FDA," and that "[i]n these analyses, Roxadustat was comparable based on a commonly applied non-inferiority margin of 1.3." Statement #9.

- . . . in response to analyst questions, Neff stated that the Company felt the ITT results were what "describe[ed] the situation most effectively," and asserted that an upper bound on the hazard ratio of 1.3 under the ITT analysis was the "safety evaluation standard the FDA usually asks for." Statement #19.

- Yu stated that FibroGen was "using the conventional standards of noninferiority, which is widely published for assessment of CKD anemia and have previously been used by [the FDA] for assessment of cardiovascular safety in similar types of composite endpoints … that standard has been 1.3 for upper bound of 95% confidence interval. If we use that standard, the answer is yes, we have achieved non-inferiority." Statement #20.

- FibroGen: The press release expressly clarified that for NDD patients, the results were based on the "ITT analysis agreed with the FDA" and that the "[r]isks of MACE, MACE+, and all-cause mortality in Roxadustat patients were comparable to placebo in the ITT analyses based on a reference non-inferiority margin of 1.3." Statements #32, 38.

- The 10-Q added that in FibroGen's "pre-NDA meeting, the FDA agreed that the ITT analysis would be our primary cardiovascular safety analysis method for non-dialysis in the U.S. as it uses on-treatment and post-treatment long term followup (until a common study end date) to

> account for the higher drop-out rate in the placebo arm. The figure below shows that in the 4,270 pooled non-dialysis patients (OLYMPUS, ANDES, and ALPS), the risk of MACE, MACE+, and all-cause mortality in Roxadustat patients were comparable to that in placebo patients based on a reference non-inferiority margin of 1.3." Statements #38, 45.
>
> - Conterno: In response to another analyst inquiry regarding whether the upper bound of the confidence intervals that was pre-agreed with the FDA was 1.25 or 1.3 for noninferiority, Conterno stated that "in non-dialysis, we basically show comparability relative to placebo. With regards to the 1 point to any measures of excess risk, you mentioned 1.25 or 1.3, I think I said in a number of different occasions that we do not have a pre-agreed noninferiority margin with the FDA." Statement #84.

The words "reference," "standard," "conventional," and "usually" do not imply any certainty; therefore, merely referencing a commonly applied standard does not indicate falsity. In fact, Conterno made clear that there was no noninferiority margin agreement with the FDA. Statement #84 ("I think I said in a number of different occasions that we do not have a pre-agreed noninferiority margin with the FDA."). Neff's full statement similarly shows that no such agreement was made:

> **[E]ven though these maybe aren't the measures that will ultimately be the ones that are evaluated**, they are an ultimate **safety evaluation standard the FDA usually asks for** whether you pose it or not. So everybody felt like this is something that's very descriptive and very informative. **I would hesitate to do anything else beyond talking about the ITT results because we do not have a specific agreement with FDA on method of analysis. And as such, it's a little presumptuous.**

Statement # 19. Statements #9 and #32 point out that Defendants agreed on an ITT analysis with the FDA but refer to the non-inferiority margin as merely "commonly applied" and "reference . . . margin." *See* Statements #9, 32, 38.

Nevertheless, allegations that data was manipulated to conform to these margins survive. For example, Plaintiff's allegation that Defendants' post-hoc manipulation of the analysis in the NDD group "resulted in an upper bound hazard ratio for the key MACE and ACM endpoints of 1.24 and 1.23, respectively—i.e., below the 1.25 goal—when the actual FDA prespecified analysis exceeded 1.25"—is still relevant. CAC ¶ 83. Defendants argue that it makes no sense that FibroGen would have lied about the 1.25 non-inferiority margin because all pooled safety results

presented using the "post-hoc" stratification factors were below 1.25 anyway. Defs. Reply at 15. This argument fails; while the post-hoc manipulated analysis did not reach 1.25, CAC ¶ 55, the prespecified sensitivity analyses (that FibroGen never disclosed to investors and were disclosed by the FDA for the first time during the AdCom) exceeded both the 1.25 and 1.3 margins. CAC ¶¶ 175, 183, 204, 228. As such, there was sufficient reason for FibroGen to lie about the 1.25 figure. As such, the CAC survives to the extent that Defendants represented that the hazard ratios fell below 1.3 when it, in fact, allegedly exceeded 1.3. *See id.*

4. Scienter

A complaint alleging securities fraud under § 10(b) must state with particularity facts giving rise to a strong inference that the defendant acted with scienter. *See* 15 U.S.C. § 78u-4(b)(2)(A); *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 321 (2007). Scienter is "a mental state embracing intent to deceive, manipulate, or defraud." *Tellabs,* 551 U.S. at 308; *see also Metzler,* 540 F.3d at 1061. "To adequately demonstrate that the defendant acted with the required state of mind, a complaint must allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009) (quotation marks and citation omitted). "[A] court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs,* 551 U.S. at 308. "[A]n inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 314. "The inference that the defendant acted with scienter need not be irrefutable, i.e., of the 'smoking-gun' genre, or even the 'most plausible of competing inferences.'" *Id.* at 324. Unlike falsity, "The Supreme Court has emphasized that courts 'must review all the allegations holistically' when determining whether scienter has been sufficiently pled. The relevant inquiry is 'whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *Reese v. Malone,* 747 F.3d 557, 569 (9th Cir. 2014) (citing *Tellabs,* 551 U.S. at 323).

Two recent cases by the Ninth Circuit deal with scienter in the context of FDA approval:

Arena and *Endologix*. In *Arena*, the Ninth Circuit held that alleged statements were sufficiently indicative of scienter:

> **Contrary to Arena's representations to investors, it was not true that the "preclinical, animal studies" demonstrated the "long-term safety and efficacy"** of lorcaserin or "the potential risk that [it] may be toxic or cause cancer in humans." It was also not true that Arena had "all of the data in hand" or that "everything that [they had] compiled so far" was "favorable." These statements were representations about lorcaserin that Arena could not, in fact, support at the time they were made. Arena was free to express confidence in FDA approval. It might have represented that Arena was working through some requests from the FDA and was confident the data would vindicate lorcaserin. But **what it could not do was express confidence by claiming that all of the data was running in lorcaserin's favor.**

Schueneman v. Arena Pharms., Inc., 840 F.3d 698, 708 (9th Cir. 2016).

The Ninth Circuit reached a different conclusion in *Endologix*. There, the defendants assured investors that the FDA would likely approve its device despite reports of safety issues in Europe. *See Nguyen v. Endologix, Inc.*, 962 F.3d 405, 408–11 (9th Cir. 2020). Later, the company revealed that the FDA had "questions" but stated that the situation was "very easy" to remedy. *Id.* at 412. In the end, the FDA did not approve the device on the timeline the defendant represented, but the Ninth Circuit held that there was not an adequately strong inference of scienter to be drawn. *Id.* at 416, 419. The Ninth Circuit noted the implausibility of the plaintiff's theory and noted that the initial U.S. data was more promising than the European data:

> [W]hy would defendants promise the market that the FDA would approve Nellix if defendants knew the FDA would eventually figure out that Nellix could not be approved due to "intractable" and "unresolvable" device migration problems? The theory does not make a whole lot of sense. It depends on the supposition that defendants would rather keep the stock price high for a time and then face the inevitable fallout once Nellix's "unsolvable" migration problem was revealed.
> . . .
>
> Underpinning the Fourth Circuit's reasoning in *Cozzarelli* was the point we recognize here: **"[i]t is improbable that [a company] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure**." *Id.* at 627. The plaintiffs' "inference of fraud based on the supposed impossibility of [a successful trial] [wa]s thus not even plausible, much less convincing." *Id.* This was so in *Cozzarelli* even though the defendants there, unlike those here, sold some of their stock in the company while the study was ongoing. *Id.* at 622, 627–28; *see also*

> *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (affirming dismissal of securities fraud complaint because, *inter alia*, "**the initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure**").

Id. at 415–16. The Ninth Circuit also noted that during the first year, the defendants had favorable studies. *Id.* at 419. Then, in the second year, the defendants "disclosed that information and expressed their belief that the issue could be addressed with a narrowed IFU[.]" *Id.* Therefore, the Ninth Circuit found important that the plaintiff failed to identify sufficient factual basis as to why defendants could not have believed that a revised IFU would allow the FDA to approve the product. *Id.*

a. Plausibility of Scienter Given Post-Hoc Changes

Defendants rely on *Endologix* to argue that Plaintiffs' theory has already been rejected as nonsensical by the Ninth Circuit. Defs. Mot. at 22 (citing *Endologix*, 962 F.3d at 415; *Patel v. Seattle Genetics, Inc.*, 2018 WL 2359137, at *9 (W.D. Wash. May 24, 2018) (finding no scienter where defendants "cooperat[ed] with the FDA" and "expended significant time and money to develop" drug while adverse events would "inevitably" be discovered and drug would "be shut down")). According to Defendants, Plaintiffs' allegations are unavailing for the same reason that it makes no sense that a company would conspire to artificially inflate the Company's stock price even though they knew the truth would eventually come out during the FDA's review of the Roxadustat NDA and face an inevitable fall out.[13] Defendants point out that Plaintiffs have not excluded the possibility that their analyses were "the honest analysis and conclusions of their authors." Defs. Reply at 8. Furthermore, given the drug's approval in Europe, it was not unreasonable for defendants to believe in their product. *Id.*

Defendants also find similarities to *AstraZeneca Securities Litigation*, 559 F. Supp. 2d 453

[13] Defendants also argue that it does not make sense that FibroGen would have colluded with its development partner, AstraZeneca. *Id.* However, this argument fails because Plaintiffs allege that AstraZeneca was also deceived by FibroGen because FibroGen was eligible to receive up to $875 million in milestone payments from AstraZeneca if it could obtain FDA approval of Roxadustat. CAC ¶¶ 251, 256.

(S.D.N.Y. 2008). Defs. Reply at 8. The *AstraZeneca* defendants similarly failed to disclose a safety issue. *AstraZeneca*, 559 F. Supp. 2d at 458, 463. Later, the AdCom voted to recommend against approval, and the FDA declined to approve the FDA. *Id.* There, the court found that it was not unreasonable for the defendants to believe in their product, given among other facts, that the drug was approved in Europe. *Id.* at 471. The court also noted that "there [was] nothing whatever to indicate that the statements made did not reflect the honest belief of the authors" such as any red flags, and that "[i]t [was] impossible to read the FDA document and the AstraZeneca document without concluding that both present the honest analysis and conclusions of their authors." *Id.*

This case is closer to *Arena* than *AstraZeneca* and *Endologix*. First, the Ninth Circuit distinguished *AstraZeneca* in *Arena*:

> Defendants contend that this case is really just like *AstraZeneca*: a good-faith scientific disagreement between the FDA and Arena about the meaning of the Rat Study and support for the Prolactin Hypothesis. If it were simply the case that this dispute turned on whether scienter could exist based on the reasonableness of Arena's interpretation of the Rat Study versus the FDA's interpretation, there would be little question Defendants would have the better argument. *See AstraZeneca*, 559 F.Supp.2d at 471 ("As of the time when the FDA Advisory Committee met ..., AstraZeneca had its side of the case and the FDA staff had its side. The FDA staff view prevailed before the Advisory Committee. This does not mean that AstraZeneca was not conscientious in advocating the drug ... before the FDA, nor does it mean that the information issued publicly over the course of more than a year was dishonest or recklessly disseminated."). However, the simple fact that Arena had an explanation for its view of the data does not mean investors would not want to know that Arena and the FDA were at odds. Arena could have remained silent about the dispute or it could have addressed its discussions with the FDA head-on. But it could not represent that there was no controversy here because all the data was favorable.

Arena, 840 F.3d at 709 (9th Cir. 2016). Here, the allegations of manipulation are closer to the false misrepresentations in *Arena* than to the reasonable belief of FDA approval in *AstraZeneca*. Unlike *AstraZeneca*, the allegations do not simply amount to honest and "favorable [analysis] . . . on the risk-benefit issue . . . backed up by a large body of details from AstraZeneca's research." *AstraZeneca*, 559 F. Supp. 2d at 471. Here, Defendants allegedly manipulated data in order to conceal known safety issues, like *Arena*'s silence regarding their dispute with the FDA.

Second, *Endologix* is not dispositive; the argument that FibroGen had no reason to invest in a drug that they knew would not receive FDA approval fails because Plaintiffs do not argue that Defendants believed that the FDA would deny approval. Plaintiffs allege that Defendants withheld the true data from *both* the market and the FDA by manipulating the nine Phase 3 safety analyses. *See* CAC ¶ 84. Plaintiffs' theory is that Defendants believed they would have obtained FDA approval through manipulation. This manipulation brings this case closer to *Arena*, where the defendant expressed confidence in FDA approval while defendants concealed safety and efficacy issues. The allegations here differ from the honest disagreement over the clinical data in *Astrazeneca*.

Furthermore, an instance of scienter is supported by *In re Rigel*, which specifically discussed post-hoc changes to data:

> **[A] post-hoc adoption of a statistical method could raise concerns regarding reliability, biased scientific methods, or even fraud**. *See United States v. Harkonen,* No. C 08–00164, 2010 WL 2985257, at *4, 7–10 (N.D. Cal. July 27, 2010). **Because there are many ways to statistically analyze data, it is necessary to choose the statistical methodology before seeing the data that is collected during the clinical trial; otherwise someone can manipulate the unblinded data to obtain a favorable result.** *Id.* at *4. Thus, the principal features of the statistical analysis usually are included in the protocol and the statistical analysis plan is finalized before the data is unblinded.

In re Rigel, 697 F.3d at 879. Defendants do not dispute post-hoc changes were made. *See, e.g.*, CAC ¶¶ 7, 71, 110, 152, 159, 175, 182, 245 ("'post[-]hoc changes' were made to every single one of nine clinical trial analyses after the data had been fully unblinded[,]" amounting to data-dredging). The dubiousness of post-hoc changes supports an inference of scienter.

b. Confidential Witnesses

Scienter is supported in this case by confidential witnesses. The CAC includes allegations by confidential witnesses in senior positions at AstraZeneca ("CW"). CAC ¶ 120. The CAC alleges that these employees uniformly confirmed that post-hoc changes to the data were made by FibroGen's most senior officers. *Id.* ¶¶ 121, 129, 130. According to the witnesses, AstraZeneca and FibroGen became aware that the FDA had identified issues regarding Roxadustat's safety data to the point that a "Black Box" warning was virtually inevitable as early as the fall of 2020—*i.e.*,

several months before Defendants were forced to reveal the truth and were telling investors the exact opposite. CAC ¶¶121, 129, 130; Opp'n at 31 (citing CAC ¶¶ 250–51).

The CW testimony here is probative.

> [W]here a complaint relies on statements from confidential witnesses, it must "pass two hurdles to satisfy the PSLRA pleading requirements. First, the confidential witnesses whose statements are introduced to establish scienter must be described with sufficient particularity to establish their reliability and personal knowledge. Second, those statements which are reported by confidential witnesses with sufficient reliability and personal knowledge must themselves be indicative of scienter.

Iron Workers Loc. 580 Joint Funds v. NVIDIA Corp., 522 F. Supp. 3d 660, 674 (N.D. Cal. 2021) (citing *Zucco Partners*, 552 F.3d at 995 (internal citations and quotation marks omitted)).

Plaintiffs have met the first prong. "The Ninth Circuit has held that numbering the confidential witnesses and describing the witnesses' job description and responsibilities constitutes a 'large degree of specificity,' especially where the witnesses' exact title is used." *Mulligan*, 36 F. Supp. 3d at 961 (quoting *Daou*, 411 F.3d at 1016). Here, each of the confidential witnesses is numbered with their specific job titles. CAC ¶¶ 121–23. CW1 was a former Senior Director of Global Marketing Roxadustat-Global Product Portfolio Strategy Cardio Renal at AstraZeneca from February 2014 until May 2021 and a senior member of the global launch of Roxadustat in China and the United States. *Id.* Regarding Roxadustat, CW 1 was responsible for leading the cross-functional team in the development of the drug's Global commercial strategy. *Id.* CW 2 is a former AstraZeneca Renal Sales Specialist who was part of the team preparing to commercialize Roxadustat from January 2019 until January 2021, and CW 3 is a former AstraZeneca Global Vice President of Renal and Anemia Therapeutic Areas from November 2013 until January 2021. *Id.* CW 3 was responsible for expanding the global anemia team delivering the first launch of Roxadustat. *Id.* These details regarding the confidential witnesses are sufficient to satisfy the first prong. *Kong v. Fluidigm Corp.*, No. 20-CV-06617-PJH, 2021 WL 3409258, at *10 (N.D. Cal. Aug. 4, 2021) (finding that the first prong was satisfied when the FAC provided titles and tenures for each CW, as well as job descriptions); *accord Impax*, 36 F. Supp. 3d at 963.

Defendants dispute the second prong because the CWs had sales or commercial roles and

were not involved in Roxadustat's clinical trials, analysis of clinical data, submission of the NDA, or communications with the FDA. Defs. Mot. at 27. However, a confidential witness need not be involved in the NDA process itself to have personal knowledge regarding the allegations. The CWs allege that FibroGen shared information about the clinical data with AstraZeneca's commercial team. CAC ¶ 124. Although the data shared was allegedly limited and provided mainly FibroGen's side of the story, this was one of the reasons for their suspicion, as full clinical trial data was normally readily available to them. *Id.* ¶¶ 121, 124–25. In addition, the CW's role as the Roxadustat sales and launch team reasonably explains their insight regarding the ongoing NDA process, which is the most critical issue in the global launch of Roxadustat. *Id.* ¶ 129 ("[T]hey backed off completely on the training, which told us that something was going on with the FDA approval.").

Defendants also argue that the CAC does not allege that any of the CWs had direct interaction with any Defendant; thus, the CW allegations do not establish personal knowledge of the defendants' mental state. While CW1 and CW2 are not alleged to have had any direct interactions with Defendants, CW3 had attended boardroom meetings during which Dr. Yu presented data. CAC ¶ 125. CW3 alleges that these data reflected the altered post-hoc analyses and that the accurate, prespecified analyses were withheld from AstraZeneca. *Id.* Regarding the black box warning, CW3 alleges with personal knowledge that "[w]e sat down with the [FibroGen] team and got an update on where things were and the direction where they were heading, and we were told that we are likely going to end up with a [Black Box] warning in the fall of 2020." CAC ¶ 130 (quotation marks omitted). Therefore, CW3 had personal knowledge from direct interaction with Dr. Yu and the FibroGen team. Furthermore, CW1 has personal knowledge as to AstraZeneca's role in launching Roxadustat and difficulties with coordinating its efforts with FibroGen. *See* CAC ¶ 121.

For the foregoing reasons, the CW allegations together raise an inference of scienter.

c. Newspaper Articles and Analyst Reports

Scienter is also supported by the reaction of the scientific and financial community to the disclosure of Defendants' manipulation of data. Plaintiffs allege that the scientific and financial

community universally concluded that Defendants' manipulations were intentional and called it the "worst case of data manipulation in years" that "could [not have] happen[ed] accidentally." Opp'n at 30; CAC ¶ 3.

Defendants dispute these reactions as pure speculation and conjecture. Defs. Mot. at 27 (quoting *In re Wet Seal, Inc. Sec. Litig.*, 518 F. Supp. 2d 1148, 1172–73 (C.D. Cal. 2007) ("[c]onclusory allegations of wrongdoing are no more sufficient if they come from a newspaper article than from plaintiff's counsel"); *Campo v. Sears Holding Corp.*, 371 F. App'x 212, 215 (2d Cir. 2010) ("press speculation about defendants' motives" are not "specific, well-pleaded facts")).

Defendants are correct that the alleged contents of the articles are conclusory. *In re Wet Seal*, 518 F. Supp. 2d at 1172 ("[N]ewspaper articles should be credited only to the extent that other factual allegations would be—if they are sufficiently particular and detailed to indicate their reliability. Conclusory allegations of wrongdoing are no more sufficient if they come from a newspaper article than from plaintiff's counsel . . ." (citations omitted)). However, while these articles and reports do not establish scienter by themselves, they lend some support to the extent that analysts and experts, including a nephrologist who was involved in the Roxadustat clinical trials, were quoted for their opinions. For example, Dr. Daniel Coyne is alleged to be a professor and a nephrologist who worked as a site investigator in the Roxadustat clinical trials and is quoted in an article: "This deeply damages the reputation of FibroGen . . . ***I feel very misled***, and I don't think there is any excuse for this. ***I don't know how this could happen accidentally***." Opp'n at 30, n.21 (emphasis in original) (quoting CAC ¶¶10, 96)).

d. Approval Around the World

According to Defendants, the fact that Roxadustat received regulatory approval in the second to eighth biggest pharmaceutical markets in the world between 2018 and 2021 shows a lack of scienter. *See* Defs. Mot. at 23; Defs. Reply at 6. This is a helpful fact for Defendants but does not undermine the plausibility of Plaintiff's allegations. Different countries have different requirements and criteria for the approval of a drug; therefore, approvals in other countries do not guarantee approval in the United States. *Cf. Endologix*, 962 F.3d at 419 (affirming dismissal and finding that the more plausible inference was that the defendants based their statements based on

the progress of the U.S. clinical trial, despite the unfavorable reports from Europe). As such, Roxadustat's favorable stance in other countries, while relevant, does not in itself negate Defendants' scienter regarding Roxadustat's potential in the U.S.

e. The April 6, 2021 Admission

Plaintiffs contend the April 6, 2021 press release was an admission of manipulation of the data. Defendants dispute that characterization. According to Defendants, the fact that a new CEO (Conterno) and a new CMO (Eisner) concluded that additional disclosures should be made shows transparency and cuts against scienter. Defs. Reply 7; Defs. Mot. at 23.

Plaintiffs plausibly respond that the press release does not indicate transparency; Defendants were forced to release their admission in April 2021 because the FDA called for an AdCom the month prior. Opp'n at 31. And Plaintiffs allege that even at this point, Defendants failed to disclose the results of crucial FDA prespecified sensitivity analyses showing that Roxadustat was less safe than placebo and Epogen in all studied populations. *Id.*; CAC ¶ 249. According to Plaintiffs, it was the FDA that later revealed the full truth about the negative safety profile for Roxadustat, and Defendants' concealment, in fact, indicates that they understood their likely effect on the market and scienter. Opp'n at 31.

Therefore, Plaintiffs have sufficiently alleged scienter because: (1) the press release admitted that Defendants made "post-hoc changes to the stratification factors," and (2) Defendants allegedly falsely touted this manipulated data for over two years. Opp'n at 29–30 (citing *Immune Response*, 375 F. Supp. 2d at 1022 ("[T]he fact that the defendants published statements [about clinical trial results] when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter."); *BioMarin*, 2022 WL 164299, at *14 (finding scienter when "the defendants allegedly told the market things that were allegedly not true and that [they] must have known were not true by their nature"); *In re MannKind*, 835 F. Supp. 2d at 815 (finding scienter "based on the falsity of the statements and Defendants' access to information contradicting those statements," particularly where "the company's interactions with the FDA" were "absolutely integral to [its] success")).

Furthermore, Plaintiffs allege that Defendants' response to analyst questions included

specific responses to questions that falsely implied that the data was sanctioned by the FDA. Opp'n at 31 (citing ¶¶ 247–48; *In re Qualcomm Inc. Sec. Litig.*, 2019 WL 1239301, at *11 (S.D. Cal. Mar. 18, 2019) ("specific [statements] … in response to questions from analysts and investors" contributed to a strong scienter inference)). An excerpt from FibroGen's November 11, 2019 earnings call following the ASN conference reads in part:

> Q: I would just like to understand, since there seems to be some investor concern about FDA agreements and FDA sign-off [from] statistical [stance/plans][14], how your general impression was of your meeting with the FDA? And why you feel confident about statistical protocols and their signing off of what you have from statistics and why you feel good about that?
>
> A: First of all, I wanted to share that we have been in dialogue with the FDA in the past 6 years. And there has been a very good understanding about what the Phase III required study would look like and including the size of the study, how to power it [for example] what's the primary endpoint and we agree on time to meet at the primary endpoint, and that's how we power for the non-dialysis and the dialysis. And we've also had a very productive dialogue with the FDA on the analysis of cardiovascular safety as well as what the efficacy requirement needs to be for this submission. And the most recent conversation with the FDA was at the end of July. And we had sent it to the FDA, a fairly comprehensive briefing package and had a very productive meeting. And walking out of it, we felt that we had all the guidance from the FDA we needed to put together a winning submission.
>
> Q: **So you feel no issue or no real concern about the hazard ratios and the [upper bounds]** and all the things that people are talking about? You look at diabetes programs and things like that, there's -- you're well within that. So you don't feel any concern about that?
>
> Yu: No, we have no concern about that. And Mike, as you know, that our regulatory assessment is not based on 1 criterion. But instead, it is based on totality of evidence such as efficacy, safety, what is the medical need. And so based on our discussions and the historical precedents in this therapeutic area and the various conversations we've had with the agency, we are very comfortable with our data where it is now.
>
> . . .
>
> Q: My second question is when are you going to talk about the [the job] as stat plan? I mean the **statistical analysis plan**, including the non-inferiority margin. Is there any pre-planned FDA meeting in the coming weeks?

[14] The exact wording is unclear form the record.

> . . .
>
> Schoeneck: I think is -- the question is when will we talk to the FDA about the statistics and the analytical plan is the question.
> . . .
>
> Yu: Okay. **So the answer to that question is that we had already talked with the FDA about analytical plan, and we had made the agreement on the analysis plan.** The **results that we have presented in the high-impact clinical session at the ASN, and the numbers I had just presented were based on the agreed analysis plan that we have made with the FDA**.
>
> Q: So the noninferiority margin of [1.3] is already in agreement or not?
>
> Yu: So we are talking about the analysis plan, meaning how do you pool, what's the pooling strategy and the analysis plan, how to analyze the data. When you talk about NI margins, you're talking about the standard for assessment, right? And as I mentioned earlier, that we expect that [all] regulators will assess the data based on the very -- all the -- on the entire application of the NDA. And based on our dialogue with FDA over the past 6 years and the data, as we have shown, we are confident that we do have what it takes for this drug to be favorably evaluated.

Docket No. 111 at 137–40. A few days later, FibroGen emailed a short seller that questioned whether Roxadustat's data reflected FDA-required analyses that: "**The data presented at [ASN] reflect the analytical methods and study pools agreed upon with the FDA**." CAC ¶ 179. Such specific answers to specific questions regarding the non-inferiority margin and analysis plans suggest that Defendants knew their importance yet consciously attempted to give a favorable impression while hiding their manipulation and unfavorable analyses.[15] These specific allegations are sufficient to plausibly allege scienter.

f. Yu's Resignation[16]

Plaintiffs further cite Yu's resignation as further evidence of scienter. According to

[15] Defendants also point out that the additional analyses in the press release had already been shared with the FDA, did not result in the withdrawal of the analyses disclosed in 2019 or indicate any issue with the integrity of the underlying data. Defs. Mot. at 23. However, the belated sharing of additional data with the FDA does not make the allegedly manipulated data any less false. Furthermore, it is not the integrity of the underlying data that is disputed, but their analysis.

[16] Yu also asks to dismiss claims to the extent any allegations are about acts or omissions occurring after Yu resigned and left FibroGen because she is no longer a "control person" under Section 20(a). However, this point is irrelevant because Plaintiffs do not allege any facts against her after her resignation.

Plaintiffs, Yu abruptly announced her resignation on November 27, 2020, on the cusp of gaining regulatory approval for its flagship drug after years of development. CAC ¶ 72. Just three weeks after the unexpected retirement, FibroGen announced that the FDA had extended the review period of the NDA for Roxadustat by three months. *Id.* ¶ 73. Therefore, Plaintiffs allege that FibroGen "pushed out its Chief Medical Officer who was directly responsible for this very data, under highly suspicious circumstances." *Id.* ¶ 72.

Yu argues that her resignation is not suspicious nor indicative of scienter. Yu Mot. at 14–15; Yu Reply at 13. Yu points out that she left with praise from the new CEO and that an internal investigation exculpated her of any inference of bad faith or wrongdoing, according to a Form 10-Q submission to the SEC. Yu Mot. at 14–15 (the new CEO praised her for her expertise and leadership on Roxadustat); Yu Reply at 13. However, the CEO's general praise of her work does not exculpate her involvement in the alleged manipulation of data. Furthermore, the submission to the SEC merely states that "[t]hose responsible for the statistical analyses believed that it was a reasonable and valid way to analyze and present the data." Docket No. 111, Ex. YY at 86. This rather conclusory and self-serving submission is hardly an exculpation of her involvement.

While Yu is correct that a resignation by itself is an insufficient indication of scienter, her abrupt resignation tends to support scienter and may be considered together with other allegations, including statements by confidential witnesses and the compensation she received, because scienter is reviewed holistically. *Reese v. Malone*, 747 F.3d 557, 569 (9th Cir. 2014) (citing *Tellabs*, 551 U.S. at 323 ("The relevant inquiry is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." (quotation marks and citation omitted)).

g. Insider Trading

Insider trading can establish scienter. However, the Ninth Circuit has long made clear that "routine business objectives, without more, cannot normally be alleged to be motivations for fraud" as "to hold otherwise would be to support a finding of fraudulent intent for all companies." *Lipton v. Pathogenesis*, 284 F.3d 1027, 1038 (9th Cir. 2002). Only "unusual" or "suspicious" stock sales by corporate insiders that are dramatically out of line with prior trading practices at

times calculated to maximize personal benefit may support a strong inference of scienter in the Ninth Circuit. *See In re Quality Sys.*, 865 F.3d at 1146; *Metzler*, 540 F.3d at 1066–67. "Three factors are relevant to this inquiry: (1) the amount and percentage of the shares sold; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's trading history." *Metzler*, 540 F.3d at 1067. Furthermore, "a lack of stock sales can detract from a scienter finding." *Webb v. SolarCity Corp.*, 884 F.3d 844, 856 (9th Cir. 2018).

Plaintiffs allege that Individual Defendants engaged in insider trading totaling over $42 million and over 80% of the total insider sales for the entire Company during the Class Period. CAC ¶ 135. Defendants dispute CAC's allegations of insider trading. According to Defendants, Cotroneo and Schoeneck both sold substantially more shares in the 31-month period before the Class Period than during it. Defs. Mot. at 25; Defs. Reply at 7. Yu, who was not employed by FibroGen the entire time, and Neff, who passed away during the Class Period, also sold more shares pre-Class Period compared to the time they were at FibroGen.[17] *See* Defs. Mot. at 24–26. Defendants are correct that these stock sales are not out of the ordinary and fail to raise a strong inference of scienter.

i. Cotroneo, Yu and Schoeneck

Yu's, Cotroneo's, and Schoeneck's pre-class period sales are larger than class period sales. Plaintiffs focus on specific instances, including Cotroneo's largest sale on December 20, 2019, which was allegedly well-timed to take advantage of a 22% increase in the stock price following FibroGen's release of false safety data on November 8, 2019. However, this single sale is insufficient to show that Defendants' trading practice fell "dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Silicon Graphics,* 183 F.3d at 986 (quotation marks and citations omitted). Plaintiffs argue that this largest sale of 59,456 shares was a deviation compared to his prior sales of 3,201 shares each on June 18, 2019 and September 17, 2019. However, these figures are taken out of context; Cotroneo had made even larger sales pre-Class Period. *See* Docket No. 110

[17] Neff passed away in August 2019, nine months into the Class Period, and Yu left the Company on December 20, 2020. *Id.*

(Kasner Decl.), App'x B. For example, Cotroneo sold 95,000 shares on August 10, 2017. *See id.* In the year the Class Period started, he had also sold 49,500 on February 16, 2018. *See id.* Although Plaintiffs seem to emphasize the temporal proximity of the sale, a three-week wait between the false statements and the stock sale is not strong compared to Plaintiffs' cited case involving sales just a week after the release of positive information. Opp'n at 32 (citing *Azar v. Yelp, Inc.*, No. 18-CV-00400-EMC, 2018 WL 6182756, at *19 (N.D. Cal. Nov. 27, 2018) ("temporal proximity between the sales and the release of" positive information "could support an inference of scienter")). Plaintiffs do not provide specific deviations in trade history for Yu and Schoeneck. As such, Yu's, Cotroneo's, and Schoeneck's trade histories do not plausibly establish scienter.

ii. Neff

Neff was alive only during the first eight months of the Class Period. Plaintiffs point out that Neff sold over fifty thousand more shares during the Class Period than the eight months before. Opp'n at 32. However, his sales were not "dramatically out of line with prior trading practices" because he sold the exact same number of 237,816 shares in 3-month intervals[18], both eight months prior to the Class Period and during the Class Period. Defs. Reply at 7. Although Plaintiffs argue that Neff unloaded 317,000 shares in the three months after the May 2019 press release, Opp. at 32, Neff sold a similar number of sales of 306,360 shares in the same period before then. Kasner Decl., App'x D. As such, while calculations using different time intervals account for some differences, Neff did not engage in stock trading that was dramatically out of line with prior trading practices.

iii. Conterno and Eisner

Conterno and Eisner joined FibroGen during the Class Period. According to Defendants, the fact that they did not sell any shares during the Class Period and that Conterno actually purchased shares cuts against scienter. Defs. Mot. at 25–26 (citing Kasner Decl. ¶ 70; *In re Leapfrog Enter., Inc. Sec. Litig.*, 237 F. Supp. 3d 943, 952 (N.D. Cal. 2017) (explaining that

[18] March 1 to May 31, 2018; June 1 to August 31, 2018; September 1 to November 30, 2018; December 1, 2018 to February 28, 2019; March 1 to May 31, 2019; June 1 to August 25, 2019.

purchase of stock "strongly weighing against scienter")).

The Court finds that these facts do not support either side in determining scienter. Conterno was required to buy and maintain ownership of shares valued at five times his base salary when he joined FibroGen. Opp'n at 32, n.25. Eisner was also required to meet minimum stock ownership amounts, and Defendants fail to provide any contrary explanation in the reply. Because there is a reasonable explanation for the purchases and lack of sales of stock, there is no inference of scienter favoring either side. *Id.*

iv. 10b5-1 Plans

Plaintiffs' attempt to establish Defendants' scienter through their stock sales fails for an additional reason. "[T]he weight of authority in the Ninth Circuit" holds that courts can consider 10b5-1 trading plans when evaluating allegations concerning scienter." *Yelp,* 2018 WL 6182756, at *4. "In general, automatic sales made pursuant to Rule 10b5-1 plans do not support a strong inference of scienter." *Rodriguez,* 325 F. Supp. 3d at 1056.

According to Defendants, each and every stock sale alleged during the Class Period was made pursuant to 10b5-1 plans. Defs. Mot. at 26. Plaintiffs respond that the fact that the sales were made pursuant to Rule 10b5-1 plans does not preclude a finding of fraud if, at the time the plans were adopted, the individual defendants were allegedly already aware of the falsity of their statements. Opp'n at 33, n.26 (citing *Applestein v. Medivation, Inc.*, No. C-10-0998 EMC, 2011 WL 3651149, at *7 (N.D. Cal. Aug. 18, 2011). Plaintiffs also point out that in *Yelp*, this Court found that it cannot conclude that the 10b5-1 plan negated any inference of scienter without reviewing the defendant's actual trading plan. *Yelp*, 2018 WL 6182756, at *19. This Court reasoned:

> To be sure, stock sales made "according to pre-determined plans *may* rebut an inference of scienter." *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1067 n.11 (9th Cir. 2008) (emphasis added). But all that can be gleaned from the Forms 4 is that Stoppelman's "[s]hares were sold pursuant to a duly adopted 10b5-1 trading plan." . . . Defendants assert that the trading plan was "executed prior to the alleged fraud," Mot. at 19, but **nothing before the Court establishes when precisely the trading plan was adopted**. **Defendants have not sought to introduce the actual 10b5-1 plan.** SEC regulations recognize "a written plan for trading securities" as an affirmative defense to insider trading allegations

> only if the insider adopted the plan "[b]efore becoming aware of the [material nonpublic] information." 17 C.F.R. § 240.10b5-1(c)(1)(i); *see Applestein v. Medivation, Inc.*, No. C-10-0998 EMC, 2011 WL 3651149, at *7 (N.D. Cal. Aug. 18, 2011) (concluding that the "fact that the sales were made pursuant to Rule 10b5–1 plans does not preclude a finding of fraud because, at the time the plans were adopted ... the individual defendants were allegedly already aware of the unblinding").

Id. at *18.

Defendants submit SEC Form 4 for each Defendant, and each transaction during the Class Period includes a footnote that "Shares [were] sold pursuant to a 10b5-1 plan." *See* Docket No. 111, Ex. AAA. Therefore, although it is not entirely clear when precisely the trading plan was adopted, they were at least adopted prior to the Class Period. Furthermore, Plaintiffs have not alleged that Defendants were already aware of the falsity of their statements at the time their plans were adopted. Plaintiffs' citation to *BioMarin* is also inapposite. Plaintiffs argue that "even if the trades were pre-planned, 'concealing [] negative information before the sale and setting the sale to occur prior to the PDUFA [(final review of the NDA submission by the FDA)] date were discretionary choices, so it is sufficient at the pleadings stage to contribute to the plausibility of the scienter allegations.'" Opp'n at 33 n.26 (quoting *BioMarin*, 2022 WL 164299, at *14). However, *BioMarin* involved defendants who had sold a much greater number of shares during the class period in comparison to the period prior to it and argued that the non-discretionary nature of the sales "lessen[ed] the implication that they were improper." 2022 WL 164299, at *14. This case is distinguishable by the fact that the pre-Class Period sales surpass the Class Period sales. Because the stock sales were made pursuant to 10b5-1 plans, they "do not support a strong inference of scienter." *Rodriguez*, 325 F. Supp. 3d at 1056. Plaintiff's attempts to argue that there is a strong showing of scienter despite their existence also fails.

h. Compensation

The Ninth Circuit has previously found that "[a] strong correlation between financial results and stock options or cash bonuses for individual defendants may occasionally be compelling enough to support an inference of scienter." *Zucco Partners*, 552 F.3d at 1004. This inference of scienter depends on the particularity of the compensation allegations:

> In *America West,* we found it **significant that the individual**

> **defendants' compensation was based "principally" on the defendant company's financial performance**. 320 F.3d at 944. The complaint at issue in *America West* established this fact by **comparison of the individual defendants' prior year's compensation with the year in question**, noting that while "none of the executive officers received option awards in 1997 for the previous year," in the year in question "America West awarded Franke 350,000 options ... [and] awarded 110,000 options to Goodmanson, 35,000 options to Parker, and 20,000 options to Garel in March 1998."

Id. at 1004–05. However, courts have distinguished general allegations that bonuses were related to a company's financial performance:

> general allegations that "executive-level bonuses were 'based in part' on [a company's] financial performance ... are inadequate to meet the heightened pleading requirements of Silicon Graphics and Tellabs." *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1005 (9th Cir.2009). **For bonuses to support an inference of scienter, the allegations in the complaint must demonstrate a strong correlation—including comparisons to previous years' bonuses—between the bonuses and the company's "bottom line**". *Id.*

In re Downey Sec. Litig., No. CV 08-3261-JFW(RZX), 2009 WL 2767670, at *13 (C.D. Cal. Aug. 21, 2009).

The CAC alleges that the individual defendants and FibroGen had compensations tied to regulatory and commercial milestones. CAC ¶ 44, 66. Plaintiffs do not provide a comparison of compensations to previous years for Conterno and Eisner (both joined FibroGen during the Class Period) and Neff (died in 2019).[19] Plaintiffs also do not provide a comparison to the previous year's compensation for Yu and Cotroneo but provide compensations for 2019 and 2020 during the Class Period. However, the compensations in 2019 are significantly higher compared to 2020, which are explicitly attributed to the submission of the Roxadustat NDA in December 2019:

1. Yu
   - 2019: $5,856,451, including $3,044,223 in stock awards, $1,886,018 in option awards, $590,000 in salary, $316,830 in non-equity incentive plan compensation, and $19,380 in other compensation. CAC ¶¶ 24, 138.
   - 2020: $3,512,764, including $1,201,950 in option awards, $1,188,450 in stock

[19] Conterno and Eisner are alleged to have each received $12.2 million and $3.9 million that year. CAC ¶ 138.

awards, $612,000 in salary, $459,000 in non-equity incentive plan compensation, and $51,364 in other compensation. *Id.*

2. Cotroneo

- 2019: $4,326,386, including $1,769,851 in option awards, $1,782,963 in stock awards, $490,000 in salary, $264,600 in nonequity incentive plan compensation, and $18,972 in other compensation. *Id.* ¶¶ 28, 138.
- 2020: $2,916,018, including $1,061,723 in option awards, $1,056,400 in stock awards, $508,000 in salary, $230,937 in non-equity incentive plan compensation, and $58,959 in other compensation. *Id.*

Plaintiffs also allege that Yu's high compensation in 2019 was directly tied to Roxadustat, as FibroGen's Proxy states that the compensation was "for her efforts in the completion of the [R]oxadustat pooled MACE safety data analyses" and "the [R]oxadustat [NDA] submission to the [FDA]." CAC ¶ 138. Yu received over $10 million in stock and option awards tied to these achievements, which accounted for the lion's share of Yu's Class Period compensation (79% in 2018; 84% in 2019; and 68% in 2020). *Id.* It can be reasonably inferred that without the data manipulation that concealed significant health risks that resulted in a unanimous decision against the drug's approval, the NDA submission would have been unlikely.

While there is no comparison of compensation to the years prior to the Class Period, the figures alleged by Plaintiffs lend some support to Plaintiffs' allegations of scienter. For example, a court found that there was a sufficiently strong correlation between the defendants' financial performance and their stock and cash awards to support a finding of scienter when the CAC alleged specific stock and cash award multipliers tying their compensation to financial performance and provided tables alleging precise amounts each executive received in base salary, stock award, and cash awards showing that the defendants' stock and cash awards far outstripped their base salaries. *See Evanston Police Pension Fund v. McKesson Corp.*, 411 F. Supp. 3d 580, 603 (N.D. Cal. 2019). Here, Plaintiffs have alleged that FibroGen's Proxy expressly ties some individual defendants' large compensation to the NDA submission relying on manipulated data. Furthermore, these options and stock awards far outweigh their salary. Both Conterno's and Yu's

salaries were merely a tenth of their other forms of compensation, most of which was stock and option awards.[20] CAC ¶¶ 24, 28, 138. Accordingly, Defendants' compensation structure suggests some degree of scienter.

i. Group Pleading

Defendants argue that Plaintiffs are required to plead scienter separately for each defendant, yet Plaintiffs group them all together to find scienter. Defs. Mot. at 26 (citing *Cheung v. Keyuan Petrochemicals, Inc.*, 2012 WL 5834894, at *4 (C.D. Cal. Nov. 1, 2012)). According to Defendants, the CAC "does not make sense" because it attributes statements and admissions to Defendants generally when the statements themselves were made by individuals. *Id.* For example, the April 6, 2021 press release is discussed as Defendants' collective admission when only Conterno made the alleged statements in that press release, and Yu had already retired from FibroGen by this time. *Id.* Similarly, the CAC also refers generally to "Defendants' … confirm[ation of] their personal participation in the pre-NDA meeting with the FDA" in July 2019, when Conterno and Eisner had not yet joined FibroGen. *Id.* However, while it is true that the CAC does often group the defendants together in its allegations, the CAC does attribute each statement to a specific Defendant in the chart summarizing each allegedly false and misleading statement. *See generally* Docket No. 91-2.

Plaintiffs have sufficiently alleged scienter, at least for some individual defendants. For example, Yu was the Chief Medical Officer who was "directly responsible for this very [manipulated] data[.]" CAC ¶ 72. Yu retired abruptly on November 27, 2020, three weeks before FibroGen announced that the FDA had extended review of the NDA. *Id.* ¶¶ 72–73. CW3 alleges that Defendant Yu presented data at the meeting that appeared incomplete. *Id.* ¶ 124. CW 3 believed that the data shown at meetings, which was later revealed as the altered post-hoc analyses, had been agreed to by the FDA at the time. *Id.* ¶ 125. Yu also received over $10 million in restricted stock and option awards that were based in large part on her efforts "in the completion

[20] Yu argues that these awards were tied to the completion of the safety studies and submission to the NDA, as opposed to their results. Reply at 13. However, this argument is unconvincing. If the study analyses were not positive, the NDA submission may not have occurred at all, or at least apparent that it was bound to fail.

of the Roxadustat MACE safety analysis" and the submission of the Roxadustat NDA to the FDA. *Id.* ¶ 138.

Specific facts alleged regarding Conterno also show an inference of scienter. On February 25, 2020, Conterno stated that he had *personally reviewed* the Roxadustat MACE safety data and that based on his extensive experience "conduct[ing] and be[ing] a part of a number of cardiovascular studies in my previous roles," the Roxadustat safety data was "extremely clean" and "highly compelling" because they had definitively shown "safety against what I think is a very high hurdle of placebo" in every single MACE category. *Id.* ¶¶ 67, 184. Statements touting manipulated analyses, despite Conterno's expertise and personal review of the data, create an inference of scienter.

Specific allegations as to other Defendants are weaker. Schoeneck and Cotroneo oversaw the submission of the Roxadustat NDA application and reviewed, approved, signed, and certified FibroGen's filing with the SEC. *Id.* ¶ 20, 22. Cotroneo received large compensations in 2020 related to Roxadustat. *Id.* ¶¶ 28, 138. Eisner discussed post-hoc changes at the April 6, 2021 press conference, which Plaintiffs allege was false because Defendants withheld analyses showing that the drug was materially inferior. *Id.* ¶ 103; Statements Chart, Statements # 83–89. Plaintiff's specific allegations against Schoeneck, Cotroneo, and Eisner, by themselves, are insufficient to create a strong inference of scienter.

j. Core Operations Theory

Finally, Plaintiffs rely on the core operations theory of scienter. The core operations inference allows a court to impute inference of scienter to individual defendants when "the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter." *Prodanova v. H.C. Wainwright & Co., LLC*, 993 F.3d 1097, 1111 (9th Cir. 2021).

> There are three circumstances under which core operations allegations can support a strong inference of scienter: (1) when they, along with other allegations, support a cogent and compelling inference of scienter, (2) when they are themselves particular and suggest that the defendants had actual access to the disputed information, and (3) in the "rare circumstances" when they are not particularized, but "the nature of the relevant fact is of such

> prominence that it would be absurd to suggest that management was without knowledge of the matter."

Id.

For example, the *In re MannKind* plaintiffs similarly alleged that the defendants misrepresented to investors facts relating to the existence and likelihood of FDA approval by stating that a study they were performing had been "blessed" and "vetted" by the FDA even though it had not, that it was designed based on FDA recommendations even though it was not, and that the FDA accepted all of the bioequivalence studies even though it had not. *In re MannKind*, 835 F. Supp. 2d at 803. The court found that the plaintiff raised an inference of scienter "based on the falsity of the statements and Defendants' access to information contradicting those statements. Moreover, the company's interactions with the FDA regarding [the drug's] approval were absolutely integral to the company's success, and it would therefore be absurd to suggest that management was without knowledge of the matter." *Id.* at 815 (internal quotation marks and citations omitted).

Defendants argue that the court cannot simply apply this inference just because the alleged fraud is related to "FibroGen's single most important drug" because doing so would "turn it into an automatic presumption of comprehensive knowledge on the part of management." Defs. Mot. at 27, n. 18 (quoting *Browning v. Amyris, Inc.*, 2014 WL 1285175, at *15 (N.D. Cal. Mar. 24, 2014)). However, the *Browning* court further explained that "[t]o avail themselves of this prong, the plaintiffs must justify their invocation based on more than a mere assertion that all CEOs should want their companies to succeed and therefore ought to know everything about their business." *Id.* The court also explicitly distinguished its case from *In re MannKind*:

> *In re MannKind Securities Actions* involved discrete events that had critical importance to the businesses at issue: stop-orders for a small number of contracts that affect a huge portion of a company's revenue and regulatory approval of a company's most important drug. It makes sense that the companies' management would or should know the relevant facts about those issues. The courts reasonably expected management to be apprised of those matters. Here, the plaintiffs appear to charge Melo with knowing whether Amyris would successfully meet its projections or not.

Id. Like *In re MannKind*, the approval of Roxadustat goes beyond a mere assertion that Defendants would have wanted the drug to succeed.

Furthermore, Roxadustat's viability was critical to FibroGen: "[A]nalysts estimated that between 85-90% of FibroGen's $3.7 billion market value '***stem[med] primarily from [the financial prospects of FibroGen's] flagship drug Roxadustat***.'" CAC ¶ 42 (emphasis in original). FibroGen is alleged to have stated that its "revenue to date" was "generated primarily from [its] collaboration agreements . . . for the development and commercialization of Roxadustat," with "substantially all" of its revenue being generated in this manner for the years covering the Class Period. *Id.* ¶ 43. FDA's approval and FibroGen's interaction with the FDA were arguably "absolutely integral to the company's success." *In re MannKind*, 835 F.Supp.2d at 803. Therefore, as in *In re MannKind*, it would be "absurd" to suggest that management did not know about the issues with their flagship product that jeopardized its FDA approval and such allegedly blatant manipulation and misrepresentation in order to save it. And like *In re MannKind*, an inference of scienter exists "based on the falsity of the statements and Defendants' access to information contradicting those statements." *In re MannKind*, 835 F. Supp. 2d at 815. The fact that Conterno and Eisner joined after the NDA submission is irrelevant if their statements were made knowing that the data was manipulated, even if they did not participate in the manipulation themselves. Therefore, both the second and third exceptions apply.

Because of the application of the core operations theory, there is an additional basis for a strong inference of scienter for each Individual Defendant. As such, Plaintiffs sufficiently pleaded scienter for all Defendants.

V. CONCLUSION

For the foregoing reasons, the Court generally **DENIES** Defendants' motion to dismiss except the following statements for failure to lack falsity:

- Statements regarding the noninferiority margin (Statements # 9, 19, 20, 29, 32, 38, 43, 45, and 84) fail to allege falsity to the extent that the CAC alleges that there was an agreement with the FDA but survive to the extent that data was manipulated to conform to those specific margins. Statements # 32, 38, 45, and 84 also survive to the extent they discuss clinical data.
- Statements #5, 34, 57, 60, 67, and 73 fail to the extent they discuss Defendants'

impression of the pre-NDA meeting and overall confidence in their NDA submission as opinions that are not actionable. Statements #5 and 34 survive to the extent they discuss clinical data.

This order disposes of Docket Nos. 106, 107, and 109.

IT IS SO ORDERED.

Dated: July 15, 2022

EDWARD M. CHEN
United States District Judge